

International Partnership for Microbicides



Microbicides to Prevent HIV/AIDS

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The Face of HIV Globally

- **Increasingly female**



*World Bank
Photos*

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

- **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





What is a Microbicide?

- Substance that can substantially prevent or reduce transmission of HIV when applied to the vagina

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

Comprehensive Approaches to HIV/AIDS

Prevention		Treatment and Care
Prior to Exposure	Time of Exposure	
Vaccines Pre-exposure prophylaxis STI treatment Behavior change	Male and female condoms Anti-retroviral rx (mother-to-child) Post-exposure prophylaxis	Anti-retroviral therapies Opportunistic infection therapies
Microbicides		Basic care

Microbicides offer a woman-initiated method to reduce HIV transmission

Current Clinical Efficacy Trials

Candidate Microbicide	Mechanism of Action	Sponsor/Funder	Trial Location
Carraguard	Entry Inhibitor	Population Council/Gates, USAID	South Africa – <i>Gugulethu, Isipingo, Durban, Gorankuwa, Shoshanguve</i>
Cellulose Sulfate Trial 1	Entry Inhibitor	Global Microbicide Program/Gates, USAID	Nigeria – <i>Port Harcourt, Lagos</i>
Cellulose Sulfate Trial 2	Entry Inhibitor	Global Microbicide Program/Gates, USAID	South Africa – <i>Durban</i> Uganda, Kenya Zimbabwe (Feb 2007)
PRO 2000	Entry Inhibitor	UK Medical Research Council/DFID	South Africa – <i>Mtubatuba, Durban, Johannesburg</i> Uganda – <i>Masaka</i> Tanzania – <i>Mwanza</i>
PRO 2000 Buffer Gel	Entry Inhibitor Vaginal Defense Enhancer	NIAID	Zimbabwe – <i>Harare, Chitungwiza</i> Zambia – <i>Lusaka</i> Malawi – <i>Blantyre, Lilongwe</i> South Africa – <i>Durban, Hlabisa</i>

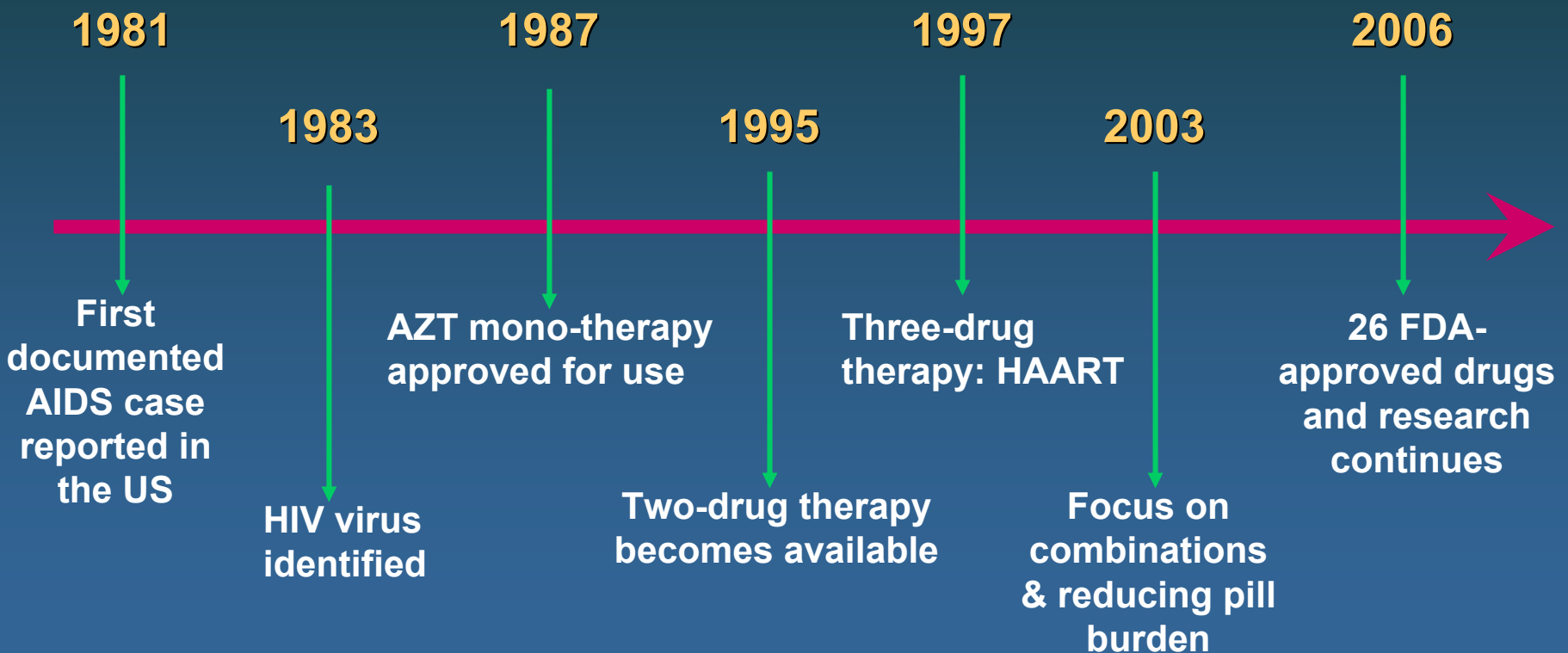


Next Generation

- Development of new microbicides – antiretroviral-based
- Future of microbicides likely in combinations – two or more mechanisms of action in one product to increase effectiveness
- Novel delivery mechanisms
 - long-acting gels
 - Intravaginal rings
- Complementing public sector and foundation support, major pharmaceutical companies have agreed to license candidate drugs to IPM and others for development as microbicides royalty-free

Realistic Expectations

First generation of microbicides likely to be only partially effective – development path similar to treatment





Urgency

- Historically, it can take decades for benefits of scientific innovation to reach the developing world
- Microbicide field committed to expediting widespread availability of any effective product, reaching those most in need first
- Microbicides must be widely available and affordable



Cost and Financial Gap

- In 2005 global community spent just over \$160 million for microbicide research and development
- Microbicide field needs nearly \$300 million in 2006 and in each of the subsequent five years to accelerate product development
- Current donors: Gates & Rockefeller Foundations, Canada, Denmark, EC, Ireland, Netherlands, Norway, Sweden, UK, US, World Bank



U.S. Funding for Microbicides

U.S. Federal Government Funding for Microbicide R&D FY 2004-2007 (US \$ in thousands)

	FY 2004	FY 2005	FY 2006	FY 2007
	Actual	Actual	Estimate	Estimate
NIH Total	\$66,168	\$66,388	\$74,461	\$74,249
CDC	\$3,425	\$5,185	\$3,435	\$3,417
Subtotal, HHS	\$69,593	\$71,573	\$77,896	\$77,666
USAID	\$21,870	\$29,760	\$39,600	\$45,000
FEDERAL TOTAL	\$91,463	\$101,333	\$117,496	\$122,666

Source: National Institutes of Health, Office of AIDS Research, March 2006.



Clinical Trial Locations

- Trials must be held in communities with high incidence of HIV infection to determine efficacy

PEPFAR Focus Countries:

- Botswana
- Cote d'Ivoire
- Ethiopia
- Guyana
- Haiti
- Kenya
- Mozambique
- Namibia
- Nigeria
- Rwanda
- South Africa
- Tanzania
- Uganda
- Vietnam
- Zambia

Current / Potential Trial Sites

- Kenya
- Malawi
- Mozambique
- Namibia
- Nigeria
- Rwanda
- South Africa
- Tanzania
- Uganda
- Zambia
- Zimbabwe



What is Needed?

- Sustained, increased financial support
 - Continued PEPFAR and USG focus on treatment, add greater support for prevention sciences
- Support for clinical trials including ARV treatment for clinical trial volunteers who seroconvert



Conclusion

With leadership, sufficient financial resources, collaborative efforts and product development expertise, women in developing countries could have access to effective microbicides within the next five to seven years.