

The Role of Vaccines and Microbicides in a Comprehensive HIV Prevention Program

'We're losing three million people a year. Treatment will slow, but not eliminate the carnage. There are 14,000 new infections daily. If we're five to ten years away from microbicides or vaccines, there's a desperate human toll to be faced between now and then. At least let the world rally to the prospect of bringing this cataclysm to an end sooner than later. And that means working on every front, on emergency footing simultaneously: care, prevention, treatment, microbicides, vaccines.'

*Stephen Lewis, UN Special Envoy on HIV/AIDS
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and Opportunistic Infections
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A Comprehensive Response to HIV/AIDS

The 2001 UNGASS Declaration of Commitment on HIV/AIDSⁱ recognized that only support for a comprehensive and sustained response to the epidemic can begin to reverse the unprecedented global impact of HIV and AIDS. Prevention of transmission, treatment, care and support for people living with HIV, and efforts to mitigate the many consequences of the epidemic are all essential and interlinked. Political and financial commitments to implementing such responses are increasing, but still fall significantly short of anticipated needs. UNAIDS estimates that \$10.5bnⁱⁱ will need to be spent each year in developing countries by 2005. Yet, at the beginning of 2004, total annual expenditures had reached only \$3.6bnⁱⁱⁱ.

Scaling up existing interventions is essential to preventing infections and saving lives today. However, even if fully implemented, the impact of current responses will be limited. Treatments can

prolong life, but they are not a cure. Similarly, present prevention options can reduce rates of HIV incidence but will not end the epidemic.^v Without new prevention options that can better meet the needs of people at risk of transmitting or contracting HIV, continued HIV incidence will place higher and higher demands on resources, making comprehensive programs unsustainable.

Investment in research and development (R&D) for new therapeutic and preventive technologies today will pay significant future dividends. In the best case, widespread availability and use of safe and effective HIV vaccines and microbicides would dramatically increase the impact of HIV prevention efforts and open the possibility of bringing the HIV/AIDS epidemic to an end.

I. A Combination Approach

Just as no single drug or medical approach is effective in treating a person living with HIV, a combination approach and an enabling environment are needed to help people prevent HIV transmission. Strategies must offer people, including those with HIV, real choices which meet their different and changing needs and that address the contexts in

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which decisions are made. Prevention responses should include activities that:

- Increase voluntary counseling and testing;
- Reduce mother-to-child transmission;
- Improve blood safety;
- Prevent and treat sexually transmitted infections (STIs);
- Offer behavioral change communications with youth and other vulnerable groups;
- Promote male and female condom social marketing and use; and
- Prevent transmission through injection drug use.^{vi}

Box 1.
Challenges in HIV prevention

Recent studies in the US have demonstrated the limitations of abstinence-only education. In one study, 88% of young American adults who pledged to abstain from sex before marriage reported choosing to break their pledges. In addition, rates of STIs among those who made pledges were similar to those among young people who had not made such a pledge.^{vii}

Significant reductions in the number of sexual partners can occur within communities and have been important in reducing HIV incidence.^{viii} However, trends may also reverse as experiences of HIV change and new cohorts become sexually active. After a significant reduction in the number of gay men reporting multiple sexual partners in the 1980s and 90s, more recent data suggests increases in some industrialized countries.^{ix}

Condom promotion has been particularly difficult within regular relationships. A review of selected countries in sub-Saharan Africa found average rates of consistent condom use among regular partners at only 7%.^x

Providing a range of options make sense as some prevention choices may conflict with personal, community, religious or cultural priorities or beliefs. Additionally, individuals' circumstances and priorities change over time. For example, the 'ABC' approach: Abstinence (or delaying first sexual activity), Being faithful (mutual fidelity) and Condom use has proven successful in some countries, such as Uganda.^{xi} However, the approach has its limitations; abstinence provides little protection where people change their minds, where childbearing is important or where sex occurs without mutual consent; partner reduction can be achieved in some settings but may be difficult to sustain or replicate in others; and condoms may be religiously unacceptable or perceived to inhibit intimacy or sexual pleasure (see Box 1). Increasing the range of available prevention options will increase the likelihood that people will be able to adopt a strategy appropriate to their needs and situation. Vaccines and microbicides would be significant prevention options in themselves, but they would also add significantly to the overall effectiveness of more general HIV prevention strategies.

II. Social and Gender Inequalities

At a global level, gender inequities present particular challenges to HIV prevention. Biologically, women are 4 times more susceptible to HIV infection than men when exposed to HIV during sexual intercourse.^{xii} Moreover, in most societies, women lack access to information and services, and may not have the power to insist on sexual and reproductive health rights or HIV prevention choices. Current prevention options, such as male condoms or mutual fidelity, require the cooperation of male partners. Although female condoms have provided an additional option in some countries, global uptake has been low, in part due to limited support for procurement and introduction. As a result women make up 58% of all people living with HIV in sub-Saharan Africa and are becoming infected 1.2 times faster than men. Young women are particularly at risk, representing 64% of people living with HIV between the ages of 15 and 24 in developing countries. As UN Secretary General Kofi Annan, has said, 'in Africa, AIDS has a woman's face.'^{xiii}

III. The Potential of Microbicides & Vaccines

Effective microbicides and vaccines would offer considerable benefits if added to existing HIV prevention efforts. Both vaccination and microbicides could put women in control of prevention decisions. Equally, vaccines and microbicides may overcome difficulties associated with condoms, such as lack of choice over contraceptive function or perceived loss of intimacy. Microbicides delivered in long-acting or sustained release formulations could be applied many hours or even days prior to sexual relations so that, like vaccines, they would not interfere with sex. Vaccines hold the promise of protection from HIV that is not dependant on repeated use. Ideally, effective vaccination will protect individuals from HIV infection before they become sexually active or begin other potentially high-risk activities.

Even with limited initial efficacy, vaccines and microbicides could add significantly to the effectiveness of current prevention strategies. Initial modeling by the London School of Hygiene and Tropical Medicine has suggested that a 60% effective microbicide used by 20% of people currently in contact with HIV prevention services in the 73 lowest income countries could avert over 2.5m infections during the 3 years after its introduction.^{xiv} A study commissioned by the World Bank and the European Commission has estimated that a 50% effective HIV vaccine delivered to 65% of adults could reduce infection rates by 25 - 60% depending on the nature of the epidemic in which it is used.^{xv}

IV. Investing in Future Success

The current challenges to effective HIV prevention make clear that new prevention options are needed. The benefits that vaccines and microbicides would offer in addition to existing prevention technologies mean that their introduction and integration into broader HIV/AIDS strategies could provide powerful means to significantly reduce HIV transmission rates, providing valuable support for both treatment and care.

In the twenty years since the discovery of HIV, only one microbicide candidate and one vaccine candidate have been fully tested in clinical trials, both with disappointing results. However, scientists agree that, given sufficient investment and focused collective effort, microbicides and HIV vaccines are possible. Efforts to accelerate the next generation of candidate products into clinical trials are underway, but more can be done. The potential health and social dividends of R&D investment are enormous, extending well beyond a single individual, country or generation. Despite this, the commercial returns on preventive technologies, particularly those that will have most impact in developing countries, are uncertain. Consequently, large pharmaceutical and biotech companies have generally invested little of their own capital in either of these fields. This must change and opportunities to encourage greater private sector contributions are needed. Still, in all cases, public sector support will be fundamental to the successful development of these new technologies and to their future introduction and use, particularly in developing countries.

A truly comprehensive response to HIV/AIDS requires both breadth and long-term vision if the efforts to scale up today are to be complemented by the necessary means to end the epidemic tomorrow.

VI. Recommended steps

- Promote the role of microbicide and vaccine R&D in national, multilateral and international strategies and agreements on HIV and AIDS;
- Increase investment in HIV vaccine and microbicide research programs, particularly efforts that prioritize the needs of developing countries;
- Support the full participation of developing countries in vaccine and microbicide development through capacity building at country level and active involvement in R&D agenda setting at an international level

- Develop incentives and opportunities to increase the participation of the private sector in bringing skills, expertise and financial resources to vaccine and microbicide efforts;^{xvi}
- Engage policy makers and communities early on in identifying strategies to ensure rapid future access and uptake of vaccines and microbicides in developing countries.

ⁱ Declaration of Commitment, United Nations General Assembly Special Session on HIV and AIDS, June 2001.

See <http://www.un.org/ga/aids/coverage>

ⁱⁱ Summers and Kates, 'Global Funding for HIV and AIDS in Resource Poor Settings', Henry J Kaiser Family Foundation, December 2003.

ⁱⁱⁱ Ibid.

^v Stover et al., 'Can We Reverse the HIV/AIDS Epidemic with an Expanded Response?' *The Lancet* Vol 360, July 6 2002.

^{vi} UNAIDS, 'AIDS Epidemic Update', Nov 2003.

^{vii} Kaisernetwork.org, "Teenagers Who Take 'Virginity Pledges,' Other Teens Have Similar STD Rates Study Says", *Daily Reproductive Health Report*, March 10 2004.

See http://www.kaisernetwork.org/daily_reports/rep_repro.cfm Rates of STIs among those pledging abstinence and those not were also comparable, with lack of sexual health knowledge among those in abstinence-only programs being cited as a factor.

^{viii} Shelton et al., 'Partner Reduction is Crucial to a Balance ABC Approach to HIV Prevention', *BMJ* Vol 328, 10 April 2004.

^{ix} See Fieldhouse (ed), 'Aids Reference Manual', NAM Publications, June 2003 for brief overview and further references.

^x See International Family Health and London School of Hygiene and Tropical Medicine, 'Are People Using Condoms? Current Evidence from Sub-Saharan Africa and Asia and Consequences for Microbicides', November 2003 available at <http://www.ifg.org.uk>.

^{xi} Hogle et al., 'What happened in Uganda? Declining HIV Prevalence, Behavior change, and the National Response.', USAID, 2002.

^{xii} Baeten and Overbaugh, 'Measuring the infectiousness of persons with HIV-1; opportunities for preventing sexual HIV-1 transmission', *Curr HIV Res* 2003; 1: 69-86.

^{xiii} <http://www.un.org/News/ossg/sg/stories/sg-29dec-2002.htm>.

^{xiv} Public Health Working Group, Microbicides Initiative 'The Public Health Benefits of Microbicides in Lower Income Countries: Model Projections', Rockefeller Foundation, 2001.

^{xv} Stover et al., 'The Epidemiological Impact of an HIV/AIDS Vaccine in Developing Countries', The World Bank, January 2002.

^{xvi} See IAVI, 'Incentives for Private Sector Development of and AIDS Vaccine', September 2004 at <http://www.iavi.org>.

About IAVI: IAVI (www.iavi.org) is a global not-for-profit organization working to accelerate the development of a vaccine to prevent HIV infection and AIDS. Founded in 1996 and operational in 23 countries, IAVI and its network of collaborators research and develop vaccine candidates. IAVI also works to assure that a vaccine will be accessible to everyone who needs it. IAVI's major financial supporters include the Bill & Melinda Gates Foundation; the Rockefeller, Sloan and Starr foundations; the World Bank; BD (Becton, Dickinson & Co.); the European Union; and the governments of Canada, Denmark, Ireland, the Netherlands, Norway, Sweden, the United Kingdom and the United States.

Policy Brief

The Policy Brief series outlines key public policy issues in the research, development and eventual distribution of HIV vaccines.

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