

## women, aids and the search for a vaccine

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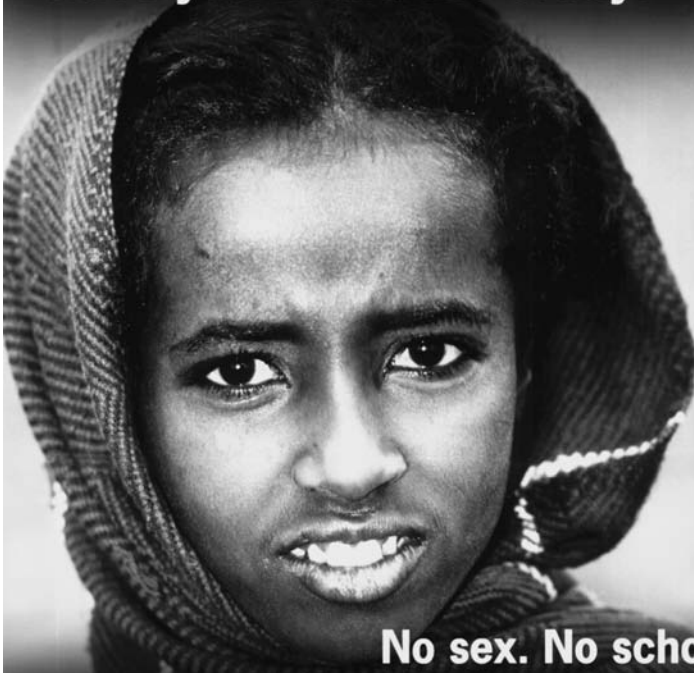
### “THE FEMININIZATION OF AIDS”

#### “WOMEN AND HIV: CAN WE AVERT CATASTROPHE?”

Headlines like these have become all too familiar, with young women—even married, monogamous women—now one of the fastest-growing risk groups for HIV infection in many parts of the world. The numbers describe a growing disaster. Nearly two-thirds of all infected 15–24-year olds worldwide are female, and women account for 57% of all sub-Saharan Africans living with HIV.<sup>①</sup> In Russia, the proportion of women among those living with HIV/AIDS climbed by 50% from 2001 to 2003,<sup>②</sup> while in the US, it's nearly quadrupled in the past two decades.<sup>③</sup>

The numbers also show that it's often not women's own behavior that puts them at risk, but that of their husbands or steady partners. For example, 90% of Indian women who test positive in antenatal clinics report being in monogamous, long-term relationships.<sup>④</sup>

**Have you heard me today?**



**No sex. No school.**

That's the choice I face. I know this makes me vulnerable to HIV but many of us can only afford to go to school by allowing our bodies to be used. This has to change.

**Equality for women helps fight AIDS.**



[www.worldaidscampaign.org](http://www.worldaidscampaign.org)



The Global Coalition  
on Women and AIDS

[womenandaids.unaids.org](http://womenandaids.unaids.org)



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Poster from the UNAIDS World AIDS Campaign, 2004. The campaign focused on how gender inequality fuels the AIDS epidemic, and how to address the many issues around HIV/AIDS that affect women and girls.

Many of the reasons for the growing HIV burden on women are rooted in cultures that limit women's control over their own lives—by restricting their access to money, property, jobs, education and healthcare, and to knowledge about their bodies and how to avoid infection. Sex between older men and adolescent girls, sex for food, shelter, or money, sexual coercion and violence are also part of the mix. Some studies also suggest a biological factor, in that women, particularly young women, may be more easily infected than men.

But the most immediate cause of women's vulnerability in most settings is their limited power to negotiate safe sex, combined with the lack of female-controlled HIV prevention methods other than the female condom, which is costly for many women, not widely enough available and can't always be used without the partner's knowledge. That, in turn, makes the development of effective *microbicides* and vaccines—completely female-controlled interventions—crucial to curbing the epidemic.

At the same time, it's important to recognize that gender stereotypes also raise men's HIV risk. Cultural concepts of masculinity often encourage them to engage in high-risk behavior (for example, having multiple sex partners) and/or to avoid seeking information on sexual health and protection from HIV, since “real men” are supposed to already know all about sex.

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#### vaccine efficacy—a gender issue?

But while having an effective vaccine could dramatically increase women's power to protect themselves, what does gender have to do with *developing* one?

More than you might think. First of all, scientists can't assume that an AIDS vaccine will work equally well in men and women. That may seem surprising, since the many different vaccines in routine use—against diseases like polio, measles, hepatitis B—seem to protect both sexes just fine. But the first

exception may be around the corner: an experimental vaccine against genital *herpes*, a sexually transmitted *virus* that causes painful sores, appears to work only in women (see chapter 30 on vaccine trials in adolescents). Further trials are now underway to confirm this finding, and to try to explain it—with most theories centering on differences in *immunity* within the linings of the male and female genital tracts, in the *mucosal tissue*. But whatever the reason, this startling result (assuming it holds up) has alerted vaccine developers to the possibility that the same thing could hold true for vaccines against other sexually transmitted diseases, including AIDS.

And the only way to find out is to test vaccines carefully for effectiveness in both men and women.

But many of the factors that make women vulnerable to HIV infection also come up in the context of AIDS vaccine trials. So if the field is to successfully test vaccines for *efficacy* in women, it's important to identify the potential social barriers in advance, and to take steps to overcome or minimize them.

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#### getting started in india: the consultative process

In early 2002, when the International AIDS Vaccine Initiative (IAVI) began working in India to prepare for vaccine trials, it was clear that gender concerns would loom large. The country has a sad history, going back several decades, of women being enrolled in contraceptive trials without full understanding of the products being tested, the risks involved and in some cases without even their knowledge that they were part of a study. This history left a legacy of deep mistrust towards clinical research, especially amongst women's health and advocacy groups.

So we began by meeting with a broad range of people, including women's and reproductive rights advocates, women's health activists, people infected and affected by HIV, non-governmental organizations and scientists, asking for their advice on how to move forward with AIDS vaccine trials in ways that were sensitive to women's needs.

In the beginning, we encountered a fair amount of skepticism. But dialog led people to recognize the potency of an AIDS prevention tool that can be used without a partner's knowledge—much as their experience in family planning had taught them that Indian women often prefer contraceptive methods they can use in this way. For many, this sealed the argument that women should take part in these trials. Many participants in these early discussions also realized that vaccine trials presented an opportunity to advance the agenda of HIV education, counseling and care geared to women.

From there, we expanded to a more formal consultative process, bringing together a group of experts and stakeholders to map out the key issues. They raised many important questions—about stigma, women's lack of autonomy, counseling and confidentiality, and making trial sites woman-friendly. On their recommendation, we established a standing Gender Advisory Board of independent experts, with the mandate of helping IAVI follow through on making its trials sensitive to women's needs, from start to finish.

Working with the trial team, this group became active on many fronts. They've been spokespeople at ethics review committees, helping to ensure that gender-sensitive procedures are integrated into *protocol* development and program design. And they've helped crystallize the many issues and strategies outlined below.

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#### issues and recommendations for gender-sensitive trials

It's too early to know what sorts of barriers will arise in recruiting women into vaccine trials in India, since the first trials will only begin in 2005. [For a perspective from the Kenyan AIDS Vaccine Initiative, which has been running *Phase I* and *I/II* trials since 2000, see chapter 25]. But we've identified a series of gender-related issues to address in trial planning, as summarized briefly below (and discussed more completely in references).<sup>⑤</sup>

- › Many women lack autonomy in making decisions, and are used to relying on husbands or partners. This is important to consider as we develop educational materials, recruitment strategies and procedures for *informed consent*. For instance, it's crucial to clearly (and often) reinforce that each volunteer has the right to make her own decision about participation, and we must scrupulously avoid even a hint of pressure or coercion.

Maintaining strict confidentiality will be critical, since any breach could lead to severe consequences for women volunteers.

- › Maintaining strict confidentiality will be critical, since any breach (related to either trial participation or HIV status), could lead to severe consequences for women in terms of stigma, blame, loss of economic support or even violence. Establishing the study site in a neutral location and under a neutral name also helps in this regard, since visits to an HIV/AIDS or STD clinic can themselves be stigmatizing.
- › Voluntary counseling and testing can be quite scary for both men and women; women's added vulnerability, especially if they turn out to be infected, requires extra care. While HIV test results should be shared only with the woman herself, there should also be support for sharing results with a partner, plus a strong effort to involve couples in VCT—which can facilitate couple communication and mutual support. If one of the two tests positive and the other negative, it can help the couple protect the negative person from infection and obtain care for the positive one. But since women are so often at risk from their partner's behavior, counseling must help them recognize this risk and empower them to protect themselves.
- › The benefits of participation must also be well-planned and well-delivered. These usually center on education and counseling to reduce infection risk, and health care for common illnesses. (For a discussion of benefits at the community level, see chapter 20).

- › The trial site should be set up in a woman-friendly way—including a convenient location and opening times, availability of childcare, and privacy for all trial-related procedures. It should also have female staff for procedures involving contact with volunteers (counseling, medical exams, etc.).
- › Ongoing training of the trial team is important for recognizing and meeting women's needs. In our case, the first training was a 3-day session held in August 2003 for the full 18-person trial staff, covering the range of issues described above. This will be followed by training in specific areas targeted to different groups—for example, counselors, ethics review committee members, protocol managers and *Community Advisory Board (CAB)* members.
- › Clear mechanisms are needed to ensure accountability. These should be based on specific indicators of gender sensitivity across all aspects of the trial. Monitoring can be incorporated into the work of the Ethics Committee.

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**beyond trials**

JUST AS traditional gender norms affect women's participation in vaccine trials, they're also likely to affect acceptability of a successful AIDS vaccine for women, or limit their access to it—ensuring that their influence on women's risk will continue even when an effective product is found.

Technologies alone will not solve these problems, or replace the need for behavioral change. So when we advocate for vaccines, we need to focus on empowering women, on increasing their access to health care and combating the social dynamics that make them so vulnerable to HIV—and on how gender stereotypes fuel the overall epidemic.

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