HIV Positive Women and Microbicides

HIV-positive women are some of the most vocal advocates for microbicides. Microbicides would represent an important and necessary tool in positive women’s lives, by protecting reproductive health and promoting healthy sexuality. Women living with HIV face the challenges of the epidemic daily, and offer a unique perspective on the broad impact microbicides could have in their lives.

We need much more information on the impact of microbicide use for HIV-positive women, but here are some of the things we DO know:

**Microbicides would benefit women living with HIV.**

Microbicides could help protect women from sexually transmitted and vaginal infections other than HIV, which can pose an even larger danger when one’s immune system is challenged. A broad-acting microbicide against multiple STDs would help prevent these dangerous infections in HIV-positive women, and may even promote healthy vaginal conditions to ward off yeast infections or bacterial vaginosis.

**Microbicides could benefit the partners and families of HIV-positive women.**

Microbicides are likely to protect both partners, giving HIV-positive women another option for helping protect their partners who may not use condoms. Some microbicides may be contraceptive and others may not. This will give positive women who want to have children the ability to do so with less risk to an HIV-negative partner. Contraceptive microbicides would give women another way to avoid an unwanted pregnancy.

As the science and research of microbicides advance, it may be possible to formulate a microbicide as a vaginal wash to help prevent mother-to-child transmission of HIV during childbirth, as an addition or back-up to anti-retroviral interventions. Microbicide researchers are also investigating a compound that could be added to breast milk to make it safe for infant feeding.

**All candidate microbicides must be safe for HIV-positive women.**

Women living with HIV may have different needs for and responses to various microbicide products. We must understand these factors before microbicides become widely available, both because positive women will be using them, and because some women may not know their status before using a microbicide. Several potential microbicides are undergoing specialized trials in order to prove they are safe for positive women to use. Phase Two and Three (large scale efficacy) trials among heterosexual women must also enroll sufficient HIV positive women to yield valid safety data.
Microbicide trials must protect the confidentiality of women living with HIV.

The stigma of being HIV positive is very real in many places. It is important that microbicide clinical trials be designed to protect the confidentiality of HIV-positive individuals.

Generally, all trials include eligibility criteria. In the case of microbicide effectiveness trials, one of the criteria may be that the woman does not already have HIV (so that scientists can evaluate whether the test product helps prevent HIV in women who are negative).

It is important that women who are screened for, but do not ultimately participate in microbicide trials for whatever reason, are not perceived as having been excluded because they are HIV-positive. In explaining the trial to potential participants and community members, researchers and involved community groups should make it clear that there are a number of reasons that women might not end up participating in a trial, and that exclusion does not mean that a woman is HIV-positive.

Some individuals have suggested that researchers enroll some HIV-positive women in the trial as a means of convincing the community that exclusion from the trial does not reflect a woman’s HIV status. Others have argued that asking women to comply with possibly complicated trial regimens without any assurance that the data generated would yield information useful to them or other HIV-positive women would be unduly burdensome.

Ensuring confidentiality is a critical ethical issue for microbicides trials, and requires trying out a number of creative approaches, as well as further research and debate.

Can HIV-positive women participate in large-scale effectiveness trials for microbicides?

In addition to the need to gather data about safety and efficacy of microbicides for women living with HIV, many positive women would like to contribute to the microbicide evaluation effort. Previously, efficacy trials have not enrolled HIV-positive women, on the assumption that one could not determine the effectiveness of the candidate microbicide at preventing HIV transmission if the trial participant were already positive. Lately, advocates and scientists have been asking if there are other ways to assess a compound’s likely effectiveness; for example, by testing whether it helps disable or kill virus shed the vagina? Researchers are exploring this option, but presently it is not yet feasible because the amount of virus that HIV-positive women shed in their vaginal secretions varies greatly from time to time and among women. Thus the absence of virus (or reductions in the amount of virus present) cannot at this time serve as a reliable marker of product effectiveness.

Many HIV-positive women are nonetheless interested in knowing whether new microbicidal candidates could help protect their sexual partners from infection. This question can be addressed through separate trials designed specifically to determine the answer.