

News Alert
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FHI Letter Regarding Further Analysis of Savvy Results

Dear Colleagues,

We wish to provide an update on the two clinical trials that examined the safety and effectiveness of a vaginal gel called SAVVY as a potential microbicide for the prevention of male-to-female transmission of HIV among women at high risk of infection. These studies, conducted by Family Health International (FHI) and partners in Ghana and Nigeria, provided no evidence that SAVVY prevents HIV infection. The results have not yet been published; a paper about the Ghanaian study is in press, and a manuscript on the Nigerian study will be submitted for publication in the next few weeks. In the meantime, we think it is important to share our findings to date.

The Ghanaian study among 2,142 women was halted by FHI in November 2005 after an independent data monitoring committee determined that the incidence of HIV was so low that the study would not be able to determine whether using SAVVY gel could reduce the rate of infection. The final results showed that eight (0.7 percent) of the women using SAVVY and nine (0.8 percent) of the women using a placebo gel had become infected during the trial.

The Nigerian study among 2,153 women was closed by FHI in August 2006 after an independent data monitoring committee determined that the trial was unlikely to find a protective effect of SAVVY if it continued. After participants were given the opportunity to complete a final visit and HIV assessment, the results showed that 21 (2.0 percent) of those using SAVVY had become infected compared to 12 (1.1 percent) of those using placebo. The difference between the two groups is not statistically significant and may be due to chance. Since the observed difference in infection rates was greater among women who indicated they used their gel most often, however, FHI is conducting additional analyses to try to better understand these results.

What do these results mean? First, the small total number of infections in both studies and the slightly different findings between the Ghana and Nigeria studies make it unlikely that, even with additional analyses, these data will yield conclusive answers to questions about any potential association between SAVVY use and risk of HIV.

Second, these studies appear to confirm that participants in HIV prevention trials tend to have lower rates of HIV infection than similar women in their communities who are not enrolled in trials. (In Nigeria, for example, 12 percent of the women screened for possible enrollment were HIV-positive and therefore ineligible for the trial.) The frequent HIV risk-reduction counseling that was offered to study participants, the treatment of sexually transmitted infections, and the provision of and education about condoms make it likely that potential HIV infections among participants in both gel groups were prevented. Women in both gel groups in Ghana and Nigeria reported that 80 percent to 90 percent of their coital acts were protected by condoms. Those planning HIV prevention trials need to consider this phenomenon during the preparation phase.

The well-being of the participants was the chief priority of Family Health International and our local partners in both trials. The trials were conducted with the highest ethical standards in accordance with the International Conference on Harmonization and with the U.S. Food and Drug Administration's guidelines on Good Clinical Practice. Participants who became infected with HIV during these studies were given counseling and referred to HIV care and support services, including antiretroviral treatment as needed. In Nigeria, the study sites were part of

healthcare institutions that participate in the President's Emergency Plan for AIDS Relief (PEPFAR) to expand access to antiretroviral drugs and HIV care, and the study established referral agreements with these PEPFAR programs. Study staff accompanied the women to the PEPFAR program office, where they were evaluated to determine whether antiretroviral treatment was indicated and provided with HIV care and support services. In Ghana, the study contracted with care and treatment organizations to provide access to treatment for women who seroconverted during their trial participation.

These studies were part of a global effort to develop a woman-controlled method to prevent HIV transmission. We are committed to continuing our work with partners around the world to develop new tools and technologies to stop HIV transmission.

With best regards,

Beth

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