

Drug stops HIV among hetero couples, not just gays

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This Monday, May 26, 2006 file picture shows Gilead Sciences Inc.'s Truvada pill in their lab in Foster City, Calif. Two studies announced Wednesday, July 13, 2011 show the pill Truvada helped prevent the spread of the AIDS virus between heterosexual couples in Africa. The drug is already used to treat people with HIV. (AP Photo/Paul Sakuma)

An AIDS drug already shown to help prevent spread of the virus in gay men also works for heterosexual men and women, two studies in Africa found. Experts called it a breakthrough for the continent that has suffered most from AIDS.

"These studies could help us to reach the tipping point in the HIV epidemic," said Michael Sidibe, executive director of the United Nation's AIDS program, in a statement Wednesday as the study results were announced.

"This is really a game changer," said Dr. Jared Baeten, the University of Washington researcher who was a leader of one of the studies.

The prevention drug is Truvada, a pill already on pharmacy shelves to treat people with HIV. It's made by Gilead Sciences Inc. of Foster City, Calif. Another Gilead drug, Viread, was also used in one of the two African studies.

Earlier research with Truvada found it prevented spread of HIV to uninfected gay men. But experts were thrilled Wednesday at the first compelling evidence that AIDS medications can prevent infection between men and women. The U.S. Centers for Disease Control and Prevention, which gave advice last fall for use of the preventive drugs among gays, is now developing guidance for heterosexuals in this country.

At the same time, national and international health officials said it's far from clear how preventive use of these drugs will play out. How many people would want to take a pill each day to reduce their risk of HIV infection? Would they stick with it? Would they become more sexually reckless?

Another issue: There already is a supply problem. In Africa, 6.6 million people are now on AIDS drugs, but 9 million people who are eligible for the treatment are on a waiting list, according to the World Health Organization. In the United States, many state assistance programs that help people access AIDS medications also have waiting lists.

The first of the new studies, run by the CDC, involved more than 1,200 men and women in Botswana. About half took Truvada each day. The other half got a fake pill.

An analysis of those who were believed to be regularly taking the pills found four of those on Truvada became infected with HIV, compared to 19 on the dummy pill. That means the drug lowered the risk of infection by roughly 78 percent, researchers said.

The second study was funded by the Bill & Melinda Gates Foundation and run by the University of Washington. It involved more than 4,700 heterosexual couples in Kenya and Uganda. In each couple, one partner had HIV and the other did not. The uninfected were given either daily placebos or one of the Gilead pills - Truvada or

Viread.

The study found 13 HIV infections among those on Truvada, 18 in those on Viread, and 47 of those on dummy pills. So the medications reduced the risk of HIV infection by 62 percent to 73 percent, the researchers said.

"Our results provide clear evidence that this works in heterosexuals," said Baeten, who co-chaired the study.

An independent review panel on Sunday said the benefit was clear-cut and stopped handing out placebos, instead offering the preventive drugs. Essentially, they deemed it unethical to withhold the medications from people who had been on placebo, Baeten said.

In both studies, participants also were offered counseling and free condoms, which may help explain the relatively low overall infection rate.

The studies were to be announced at an AIDS conference in Rome next week. But following the recommendation of the review panel to the University of Washington study, both study teams made hasty decisions to release the results.

These are the third and fourth widely reported studies of Gilead's treatments.

The first was announced last year, involving gay men in Peru, Ecuador, Brazil, South Africa, Thailand and the United States (San Francisco and Boston). Truvada lowered the chances of infection by 44 percent, and by 73 percent or more among men who took their pills most faithfully.

Experts celebrated. The CDC advised doctors on prescribing the pill along with other prevention services for gay men, based on those encouraging results.

But momentum seemed to stall in April, when an interim analysis of a study of 3,900 women in Kenya, Tanzania and South Africa did not show a benefit from Truvada. Scientists can't explain the failure in that study but one theory is that the women did not take the pill as often as they should

have, said Dr. Lynn Paxton, who has coordinated the federal agency's HIV prevention research. who coordinates the CDC's research into HIV prevention.

Gilead Sciences is a major producer of AIDS drugs. On Tuesday, United Nations health officials announced the company had agreed to allow Truvada, Viread and two other drugs to be made by generic manufacturers, potentially increasing their availability in poor countries.

That was seen as good news, but something short of a major coup.

"I wouldn't expect an immediate dramatic effect on the generic availability" of those drugs in Africa, said Tido von Schoen-Angerer, executive director for Doctors Without Borders' campaign for access to essential medicines. The agreement limits the number of additional countries that can produce the drugs, he said.

Officials say they will have to determine how much of the medicine can be produced and how much it will cost, and priorities will have to be set when it comes to who would get the drugs for prevention.

A 30-day supply of Truvada costs about \$900 in U.S. pharmacies, and the same amount of Viread costs about \$600. Prices charged in developing countries are much lower, but still can be hard to shoulder.

"Countries need to identify which populations could benefit the fastest and at the lowest cost," said Cate Hankins, chief scientific adviser at the United Nations' AIDS agency.

"There has to be some soul-searching about the costs of current drugs," she added.

Without WHO or UNAIDS guidance on how to roll out the prevention regimens, experts say it's unlikely any countries will take serious steps to do that. UNAIDS said they hoped that guidance would be ready next year.

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