

Headline
Date
MediaTitle
Section
Journalist
Frequency
Circ / Read

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21 Jul 2010
International Herald Tribune
Front Page
N/A
Daily
91,039 / 273,117

Language
Page No
Article Size
Color
ADValue
PRValue

English
1,4
511 cm²
Full Color
12,037
36,111



Study of H.I.V.-fighting gel offers new hope to women

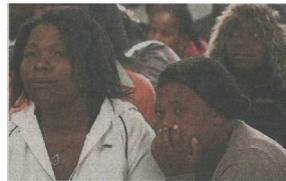
VULINDLELA, SOUTH AFRICA

Other research finds that paying girls' families can also reduce infection

BY CELIA W. DUGGER

With an AIDS vaccine still out of reach, two rigorous new studies have found different ways to sharply cut H.I.V. infections among women and schoolgirls, who make up a majority of the newly infected in sub-Saharan Africa.

After two decades in which researchers searched fruitlessly for an effective vaginal microbicide to block H.I.V., South African scientists working in two AIDS-devastated communities of South Africa, one rural and one urban, say they have finally found something that



JOAO SILVA FOR THE NYT

Volunteers in a South African H.I.V. study learning that women who used a microbicide gel reduced their risk of infection.

shows real promise.

Women who used a vaginal microbicide gel containing an antiretroviral medication widely used to treat AIDS, tenofovir, were 39 percent less likely overall to contract H.I.V. than those who used a placebo.

Those who used the gel most regularly reduced their chances of infection 54 percent, according to a two-and-a-half-year study of 889 women by Caprisa, an AIDS research center based in Durban.

Broader trials are needed to confirm the results, and it will most likely be years before the product is publicly available, but if produced on a large scale, the gel would cost less than 25 cents per application, the lead investigators estimated.

Because the trial was relatively small and the gel was nowhere close to 100 percent effective, AIDS scientists and public health officials wanted to see another trial get similar results before they undertook the large fund-raising and public education efforts that would be needed to make billions of doses of the gel, as well as the applicators, which are more expensive.

Women would then have to be persuaded to use the gel and applicators, and governments of poor countries to adopt them.

Dr. Bruce Walker, a Harvard Medical School professor who was not involved in the study, said a cheer erupted when AIDS, PAGE 4

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AIDS, FROM PAGE 1

researchers unveiled their findings to a small group of scientists last month in Durban.

"This is the first time that there's been a tool that women can use to protect themselves from becoming infected," he said. "It's a game changer."

In Vienna, where a meeting of the International AIDS Society is under way, leaders of the global fight against AIDS said they found the results of the microbicide trial very impressive. The study was published online Monday by Science magazine.

"This is very encouraging," said Michel Sidibé, executive director of Unaid, the AIDS agency of the United Nations. "It can be controlled by women, and put in 12 hours earlier, and that is empowering. They do not have to ask the man for permission to use it. And the cost of the gel is not high."

In another piece of progress against AIDS, a separate, large study in Malawi sponsored by the World Bank, and made public Sunday, found that if poor schoolgirls and their families received small monthly cash payments, the girls had sex later, less often and with fewer partners.

A year and a half after the program started, the girls were less than half as likely to be infected with the AIDS or herpes viruses than were girls whose families received no payments. The likelihood that the girls would agree to sex in return for gifts and cash declined as the size of the payments from the program rose, suggesting the central role of extreme poverty in sexual choices.

"Maybe we can combine these behavioral and biomedical interventions," said Dr. Tim Farley, a scientist with the World Health Organization involved in H.I.V. prevention research. "We need to pursue both avenues."

At a time of intensifying competition for global health dollars, when the number of people who contract H.I.V. is outstripping those put on treatment each year, pressure is mounting on African countries and donors to focus more heavily on prevention. Male circumcision is one method proven to at least halve a man's chances of H.I.V. infection.

Scientists say the success of the \$18 million microbicide trial, largely paid for by the U.S. Agency for International Development, and the study on cash payments offer hope to girls and women in Africa, who have higher rates of H.I.V. infection than men and often less power in relationships to protect themselves.

There have been other signs of progress. A new Unaid study found that H.I.V. prevalence among young people had declined more than 25 percent in 15

of the 21 countries most affected by AIDS. In eight countries, the agency found evidence of positive changes in sexual behavior among young people; for example, delaying having sex, having fewer partners and increasingly using condoms.

While cash payment programs are already spreading in Africa, the antiretroviral gel will take longer, according to the husband-and-wife team of epidemiologists who led the study. They are Dr. Salim S. Abdool Karim, Caprisa's director, and Dr. Quarraisha Abdool Karim, associate scientific director.

"I would be very sad if we had to sit around a table three years from now and we don't have the confirmation and regulations in place," Dr. Salim Karim said.

Dr. Quarraisha Karim noted that "for women, it certainly is a turning point."

The women who participated in the study — in the city of Durban and in the rural community of Vulindlela, in the rolling hills of KwaZulu-Natal — used the gel up to 12 hours before and after sex. Usually their partners were not aware of it. Tissue biopsies found levels of tenofovir that were 1,000 times what they would have been in the blood if the drug had been taken by pill, the team said.

The success follows years of disappointing results in trials of other microbicides that were found to be ineffective, or even to raise a woman's risk of H.I.V. infection. There are other trials under way that use tenofovir in gel and pill forms.

Gilead Sciences, the California-based biopharmaceutical company that developed tenofovir, donated 30 kilograms, or about 65 pounds, of the active ingredient for the study. It has also relinquished any claim to royalties on the gel if it is distributed in Africa and poor countries in other parts of the world.

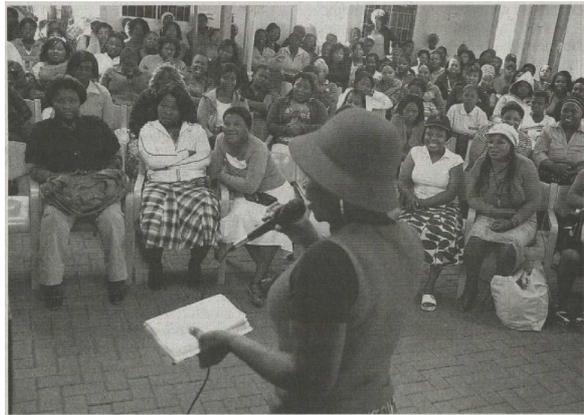
In Vulindlela, women have a desperate need for a way to protect themselves. H.I.V. testing of pregnant women in the area has found that one in 10 is already H.I.V.-positive by 16; half are infected by 24.

Before antiretroviral treatment became available here, the graveyards were crowded every weekend with funeralgoers. Fewer people are dying now, but many young women are still getting infected.

Xoliswa Mthethwa, 26, who was part of the study, said she told her boyfriend about the gel and he was very supportive. If it worked, she said, "I'd be the first person to go buy it."

Donald G. McNeil Jr. contributed reporting from Vienna.

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JOAO SILVA FOR THE NEW YORK TIMES

These volunteers, who took part in the breakthrough H.I.V. study, live in a part of rural South Africa where one in 10 women is H.I.V.-positive by age 16, and half are by age 24.