

## 3 big developments make AIDS outlook more hopeful

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FILE - This May 26, 2006 file photo, shows a close up of Gilead Sciences Inc.'s Truvada pill in a lab in a Foster City, Calif. Scientists have an exciting breakthrough in the fight against AIDS. Daily doses of Truvada, a pill already used to treat infection with HIV, the virus that causes the disease, helped prevent healthy gay men from catching it through sex with an infected partner. In a study of gay and bisexual men in six countries, the pill, cut the risk of infection by 44 percent when given with condoms, counseling and other prevention services. Men who took their pills most faithfully, at least 90 percent of the time, had even more protection \_ 73 percent. (AP Photo/Paul Sakuma, File)

(AP) -- In the nearly 30 years the AIDS epidemic has raged, there has never been a more hopeful day than this. Three striking developments took place Tuesday: U.N. officials said new HIV cases are dropping dramatically worldwide. A study showed that a [daily pill already on](#)

[pharmacy shelves could help prevent new infections](#) in gay men. And the pope opened the way for the use of condoms to prevent AIDS.

"I don't know of a day where so many pieces are beginning to align for HIV prevention and treatment, and frankly with a view to ending the epidemic," said Mitchell Warren, head of the [AIDS Vaccine](#) Advocacy Coalition, a nonprofit group that works on HIV prevention research. "This is an incredibly opportune moment and we have to be sure we seize it."

President [Barack Obama](#) said the groundbreaking research on the AIDS drug "could mark the beginning of a new era in HIV prevention."

The U.N. report said that new cases dropped nearly 20 percent over the last decade and that 33.3 million people are living with HIV now.

"We can say with confidence and conviction that we have broken the trajectory of the AIDS pandemic," said UNAIDS Executive Director Michel Sidibe in Geneva.

Health officials credit part of the decline to wider [condom use](#), and on Tuesday, in a historic shift in church teachings, the Vatican said that using a condom is a lesser evil than infecting a sexual partner with HIV.

Condoms remain the best weapon against AIDS, and the new prevention pill is not the chemical equivalent. But scientists called it a true breakthrough. The pill, Gilead Science's Truvada, is already used to treat people with HIV. A three-year global study found that daily doses cut the risk of infection in healthy gay and bisexual men when given with condoms, counseling and other prevention services.

The drug lowered the chances of infection by 44 percent, and by 73 percent or more among men who took their pills most faithfully.

Researchers had feared the pills might give a false sense of security and make men less likely to use condoms or to limit their partners, but the opposite happened - risky sex declined.

The results are "a major advance" that can help curb the epidemic in gay men, said Dr. Kevin Fenton, AIDS prevention chief at the U.S. Centers for Disease Control and Prevention. But he warned they may not apply to people exposed to HIV through male-female sex, drug use or other ways. Studies in those groups are under way.

Because Truvada is already on the market, the CDC is rushing to develop guidelines for doctors who want to use it to prevent HIV, and urged people to wait until those are ready.

As a practical matter, price could limit use. The pills cost \$5,000 to \$14,000 a year in the United States, but roughly \$140 a year in some poor countries where they are sold in generic form.

Whether insurers or government health programs should pay for them is one of the tough issues to be sorted out, said Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases.

"This is an exciting finding," but it "is only one study in one specific study population," so its impact on others is unknown, Fauci said.

His institute sponsored the study with the Bill & Melinda Gates Foundation. The findings were published online by the New England Journal of Medicine.

It is the third AIDS prevention victory in about a year. In September 2009, scientists announced that a vaccine they are now trying to improve protected 1 in 3 people from getting HIV in a study in Thailand. In July, research in South Africa showed that a vaginal gel spiked with an [AIDS](#)

[drug](#) could cut nearly in half a woman's chances of getting HIV from an infected partner.

Gay and bisexual men account for nearly half of the more than 1 million Americans living with HIV. Worldwide, more than 7,000 new infections occur each day. Only 5 to 10 percent of global cases involve sex between men.

"The condom is still the first line of defense," because it also prevents other sexually spread diseases and unwanted pregnancies, said the study leader, Dr. Robert M. Grant of the Gladstone Institutes, a private foundation affiliated with the University of California, San Francisco. But many men don't or won't use condoms all the time, so researchers have been testing other prevention tools.

AIDS drugs already are used to prevent infection in health care workers accidentally exposed to HIV, and in babies born to infected mothers. Taking these drugs before exposure to the virus may keep it from taking hold, just as taking malaria pills in advance can prevent that disease when someone is bitten by an infected mosquito.

The strategy showed great promise in monkey studies using tenofovir (brand name Viread) and emtricitabine, or FTC (Emtriva), sold in combination as Truvada by California-based Gilead Sciences Inc.

The company donated Truvada for the study, which involved about 2,500 men at high risk of HIV infection in Peru, Ecuador, Brazil, South Africa, Thailand and the United States (San Francisco and Boston). The foreign sites were chosen because of high rates of HIV infection and diverse populations.

More than 40 percent of participants had taken money for sex at least once. At the start of the study, they had 18 partners on average; that

dropped to around six by the end.

The men were given either Truvada or dummy pills. All had monthly visits to get HIV testing, more pills and counseling. Every six months, they were tested for other sexually spread diseases and treated as needed.

After a median follow-up of just over a year, there were 64 HIV infections among the 1,248 men on dummy pills, and only 36 among the 1,251 on Truvada.

Among men who took their pills at least half the time, the risk of infection fell by 50 percent. For those who took pills on 90 percent or more days, risk fell 73 percent. Tests of drug levels in the blood confirmed that more consistent pill-taking gave better protection, and in one subgroup, the reduction in risk was 92 percent.

The treatment was safe. Side effects were similar in both groups except for nausea in the Truvada patients. Weight loss also was more common in the drug group, but it occurred in very few. Further study is needed on possible long-term risks.

All participants will get a chance to take Truvada in an 18-month extension of the study to see if men will take the pill more consistently if they know it helps, and whether that provides better protection. About 20,000 people are enrolled in other studies testing Truvada or its component drugs around the world.

The government will review all ongoing prevention studies, such as those of vaccines or anti-AIDS gels, and consider whether people getting dummy medicines should now get Truvada since it has been shown effective in gay men.

Gilead may seek approval to market Truvada for prevention, said Dr.

Howard Jaffe, president of the company's philanthropic arm. Doctors can prescribe it for this purpose now if patients are willing to pay for it, and some already do.

Some people have speculated that could expose Gilead to new liability concerns, if someone took the pill and then sued if it did not prevent infection.

"The potential for having an intervention like this that has never been broadly available before raises new questions. It is something we would have to discuss internally and externally," Jaffe said.

Until the CDC's detailed advice on Truvada is available, the agency said gay and bisexual men should use condoms consistently and correctly, get tested and treated for [HIV](#) and other sexually transmitted diseases, get counseling and reduce their number of sexual partners.

**More information:**

CDC advice: [www.cdc.gov/nchhstp/newsroom](http://www.cdc.gov/nchhstp/newsroom)

AIDS information: [www.aidsinfo.nih.gov](http://www.aidsinfo.nih.gov)

and [www3.niaid.nih.gov/topics/HIVAIDS/](http://www3.niaid.nih.gov/topics/HIVAIDS/)

Pill study: [www.iprexnews.com](http://www.iprexnews.com)

Journal: [www.nejm.org](http://www.nejm.org)

UNAIDS: [tinyurl.com/krq7kr](http://tinyurl.com/krq7kr)

Prevention efforts: [www.avac.org](http://www.avac.org)

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