

Pills to prevent HIV raise many questions: studies

July 11 2012, by Kerry Sheridan

Various trials examining the use of anti-retroviral drugs in healthy heterosexuals as a way to prevent HIV have shown drastically different results, research showed Wednesday.

The findings of three major studies in Africa, published in the [New England Journal of Medicine](#), raise many questions about which groups would likely benefit and how to manage such treatments in the future, doctors said.

The approach is known as pre-exposure prophylaxis, or PrEP, in which healthy people take [antiretroviral drugs](#) -- the kind used to treat people with HIV -- in order to prevent getting the virus during sex with HIV-infected partners.

One study detailed in the journal which included [heterosexual couples](#) -- each with one HIV-positive partner, one HIV-negative -- showed a 67 to 75 percent reduced risk of getting HIV among uninfected partners taking the drugs.

The study, known as Partners PrEP, ran from 2008 to 2010 in Kenya and Uganda and included more than 4,700 couples. It randomly assigned the HIV-negative partners to once-daily tenofovir, a combination of [tenofovir-emtricitabine](#), or a placebo.

Both treatments showed "significant" and a "similar magnitude" of protection for both men and women, the study said.

[Adherence](#) to the [drug regimen](#) was also high in this study, with 82 percent of samples from randomly selected participants showing detectable drug levels, and study authors estimating an overall 92 percent adherence rate.

Another study detailed in the journal however was stopped early in April 2011 because the group receiving the drug did not show any better level of protection than the group taking the sugar pill.

That study, known as FEM-PrEP, was a [randomized trial](#) of 2,120 women in Kenya, South Africa and Tanzania.

Thirty-three women taking the drug became infected with HIV, compared to 35 taking the placebo.

The study also showed a much lower rate of adherence to the medication regimen (40 percent) and a much higher rate of reported side effects such as [nausea](#), vomiting and kidney or liver abnormalities.

Since many of the women in the study reported viewing themselves at low-risk for acquiring HIV, this may have contributed to their failure to take the drug regularly, the study authors said.

A third study, called TDF-2, enrolled 1,219 men and women in Botswana, and showed that pre-exposure prophylaxis had an efficacy rate of about 62 percent in sexually active heterosexual adults.

Previous studies on men who have sex with men have shown that the approach could reduce transmission of HIV by 44 percent overall, though much higher success rates were seen in men who took the pills most regularly.

"Why the results differ across the various studies reported to date is

unclear," said an accompanying editorial by Myron Cohen from the University of North Carolina and Lindsey Baden of Brigham and Women's Hospital in Boston.

Learning more through future study is important because PrEP is increasingly being seen as a part of an integrated HIV prevention approach, they wrote.

Also, an advisory panel to the US Food and Drug Administration earlier this year recommended approving the first ever pill for HIV prevention. A decision is expected in September.

Therefore, doctors need to consider how to manage such an approach with patients, the authors said.

Questions to consider include which populations are best suited, when to start and stop treatment, how to avoid the risk of [drug](#) resistance, what long-term side effects may include, and how to make sure the treatment does not encourage risky behavior such as unprotected sex.

"Concern about the management of pre-exposure prophylaxis of HIV infection should not detract from the potential importance of the intervention," Cohen and Baden wrote.

"The health care provider who recommends pre-exposure prophylaxis needs a management plan that recognizes the effects of the intervention on the patient's sexual behavior, safety and well-being as well as the ramifications of the intervention for the health of the public."

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