Don’t Delay HIV Prevention for Gay and Bi Men

October 26, 2011 By David Ernesto Munar

Lives will be saved when the Food and Drug Administration puts its stamp of approval on a groundbreaking preventative approach called pre-exposure prophylaxis, or PrEP, recently found to reduce HIV infections.

With PrEP, people who are not infected with HIV take a daily pill, usually used to treat the disease, to help prevent infection -- as part of a broad HIV prevention approach that includes condoms and safer-sex counseling.

But the longer the FDA waits before beginning its review of the HIV medication Truvada for prevention, the more lives will be unnecessarily lost. This is particularly true for those at greatest risk: gay and bisexual men.

We urge the FDA to immediately begin its review for approval of Truvada for PrEP for gay and bisexual men.

Last year the iPrEX trial, touted as the scientific breakthrough of the year by TIME magazine, found that gay, bi and other men who have sex with men who took Truvada, along with counseling and condoms, had 42 percent fewer HIV infections than with counseling and condoms alone. Among those who used the prevention pill most consistently, the drop in infections was far greater.

And remember the sobering context: between 2006 and 2009, the number of young gay African-American men infected with HIV in the United States increased by 48 percent, according to the U.S. Centers for Disease Control.

According to the same grim estimates, gay and bi men account for more than half of all new HIV infections in the same time period. Young gay men saw a 34-percent spike in HIV infections in that three-year span.

The clock is ticking. While we support more research into Truvada’s effectiveness as a prevention tool for heterosexuals, we strongly recommend making this medication available for PrEP for gay and bi men as soon as possible.

Why the distinction? Simply put, the success of PrEP has been clear in trials of PrEP for gay, bi, transwomen and other men who have sex with men, whereas the results for heterosexuals have been mixed.

Two major trials in Africa also found that PrEP reduces HIV infection risk in heterosexual men and

women substantially. But two other studies presented conflicting information about how PrEP works in women specifically. Many researchers feel that more information is needed to understand how PrEP interacts with hormonal contraception or how it may impact pregnancy. Necessary efforts to better understand the use of PrEP in heterosexuals should not delay access to a potentially lifesaving form of HIV prevention for gay and bi men, however.

HIV prevention has never been a one-size-fits-all issue. And this particular approach is not without its controversy. As experts pointed out in an Oct. 10 New York Times article, inconsistent adherence to PrEP could negate its effectiveness.

But in more than 30 years of fighting this epidemic, we have learned that a variety of approaches is needed for different populations, and that a combination of proven prevention approaches is the best way to drive down HIV infection significantly. Before the results of the heterosexual PrEP studies were announced, the FDA and the makers of Truvada, Gilead Sciences, were reported to be ready to move quickly to consider approval of PrEP for gay and bi men, who would clearly benefit from the approach.

Now, however, it looks like the FDA review of PrEP for this population may be put on hold for another six months or longer while the agency awaits more data pertaining to heterosexuals.

This is a national health crisis. We desperately need new strategies and tools to reduce the rapidly increasing rates of HIV infection in young gay and bi men, especially men of color.

FDA's approval of PrEP is imperative. The drugs used in PrEP were approved for treatment years ago, but FDA approval of their use for prevention -- in any population -- is essential to promoting equitable access, appropriate use and insurance reimbursement.

Approval by the FDA will also influence the availability of the multipronged approach in the countries hardest-hit by HIV/AIDS in Africa, Asia and Eastern Europe, which look to the agency for assurance that a new therapy is safe and effective.

For example, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), the largest international program for HIV treatment and prevention in developing countries, considers FDA approval a critical step in providing access to PrEP.

Delaying FDA review of PrEP for gay and bi men is bad health policy that could result in many preventable new HIV infections.

That's why my colleagues and I have sent an open letter to the FDA and Gilead Sciences, urging them to move forward promptly with a review of PrEP as an HIV prevention tool for this highly affected population. This activity can happen in parallel with continued research into the use of PrEP among heterosexual populations.

With a new infection every nine and a half minutes in the United States, approval delayed is approval denied. Asking gay, bi and other men who have sex with men to wait six months longer for a tool that we know can make an enormous difference today is asking too much -- and forsaking too many lives.

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