Are We Ready for PrEP?

December 7, 2007 By David Evans

The potential success of a large pre-exposure prophylaxis (PrEP) trial is prompting the U.S. Centers for Disease Control and Prevention (CDC) to begin preparations now, say officials at the 2007 National HIV Prevention Conference in Atlanta.

PrEP trials underway are studying the use of antiretroviral drugs—either Viread (tenofovir) or a combination of Viread and Emtriva (emtricitabine)—in high-risk HIV-negative people to determine if they are safe and effective in preventing new HIV infections. The first interim analysis of a large trial is to be reported in the fall of 2008. If these early data indicate that PrEP is effective, it is expected that interest in these agents as preventive treatment will increase significantly among health care providers where they are available.

In an effort to prepare for this heightened interest and potential upswing in preventive prescribing, Dawn Smith, MD, MPH, of the CDC led a panel discussion to assess the possible challenges to implementing PrEP in the United States. Smith said that the CDC is beginning early preparations, despite not knowing for certain whether PrEP will work, because early planning significantly helped the rollout of another successful prevention strategy—the use of Retrovir (zidovudine) to help prevent mother-to-child HIV transmission.

Some of the most important unanswered questions, if PrEP is successful, include which populations should be offered PrEP, where and how it should be distributed, how it should be used and who will pay for it. Panelists also questioned the likelihood of PrEP acceptance and usage in a variety of high-risk communities, including injection-drug users, black gay and bisexual men, and black heterosexual women whose partners are at high risk for infection.

Panelist Don Des Jarlais of Beth Israel Hospital in New York City suggests that for injection-drug users, the ideal distribution locations include drug treatment centers, methadone maintenance programs and syringe-exchange sites. The downside to this approach, however, is that the injection-drug users at highest risk for infection are unlikely to frequent these kinds of services. Proper adherence, of a drug or combination of drugs that must be taken every day, is also an issue for injection-drug users.

Addressing heterosexual women, Dázon Dixon-Diallo underscored the high rates of pregnancy among young women of color, despite their relatively easy access to contraception. Dixon-Diallo, a panelist from SisterLove in Atlanta, pointed out that there are psychological and sociological factors that lead many young women to forgo birth control pills and condoms as proof of trust in

their sex partners and the fidelity of the relationship, often despite evidence to the contrary. She feels that that this struggle—getting women to acknowledge their risks—will be a significant barrier when it comes to implementing the use of PrEP in this population.

In communities of young gay and bisexual men of color, where HIV rates rival those in sub-Saharan Africa, one barrier could be their disconnection from and mistrust of traditional health care providers and systems. According to panelist Ron Simmons of Us Helping Us in Washington, DC, antiretroviral drugs, including Retrovir (zidovudine) in particular, have a bad reputation among many in the African-American community. The panelists were concerned that these factors could limit uptake among young men of color.

Nearly every panelist raised the issue of the medical community's willingness to prescribe PrEP, and the public's willingness to pay for it, when it is sex and drug use that are the predominant modes of HIV transmission in the United States.

Wayne Duffus, MD, of the South Carolina State Department of Health, sought to address that first issue. He surveyed 238 health care providers, mostly from STD clinics and public health care settings in South Carolina, about their knowledge of PrEP and possible willingness to prescribe it, should it be found effective. Although 52 percent had heard of PrEP, only 8 percent were aware of the PrEP trials currently underway. When asked if they would be willing to prescribe PrEP should it be found effective, 28 percent said yes, 18 percent said no, and nearly 50 percent said that they weren't sure. When asked if they felt that PrEP could cause people to give up on traditional safer-sex practices, such us condom use, 72 percent said yes.

When it comes to how PrEP will be paid for, there are no obvious answers. According to Smith, Ryan White programs—which currently cover both health care and medications for people with HIV who can't otherwise afford it—have strict laws stating that the funds can only be used in people who are HIV positive. It is unclear, at this moment, if insurance companies or public payers like Medicaid will cover the costs of PrEP. Some panelists pointed to the controversies over who should receive Gardasil, the human papillomavirus (HPV) vaccine to prevent cervical cancer, and who will pay for it.

As was obvious from the panel discussion, there are a number of areas that will demand attention if PrEP is found to be effective. There are no easy answers, but early preparation, as the CDC is suggesting, will be critical if we are to get PrEP to the people who need it most.

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