AIDS Conference Bolsters the Use of HIV Meds as Prevention

An overview of studies presented at the International AIDS Society Conference in Vancouver, British Columbia.

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In 2011, the interim results of the famed HPTN 052 study of mixed-HIV-status heterosexual couples showed that starting antiretrovirals (ARVs) reduced the risk of transmitting the virus by 96 percent. The study was named “Breakthrough of the Year” by the journal Science as its findings brought HIV prevention into a new, exciting era, one in which ARVs play a central role.

A year later, so-called biomedical prevention strategies expanded to include HIV-negative people when the commonly used ARV Truvada (tenofovir/emtricitabine) was approved in the United States for use as pre-exposure prophylaxis (PrEP) against the virus.

Meanwhile, definitive proof remained lacking that the rush to get HIV-positive people on treatment wasn’t ignoring possible net harms of starting ARVs early, subverting individual medical autonomy to larger public health goals. Finally, in May 2015, results from the randomized controlled START trial provided gold-standard scientific evidence that starting treatment soon after diagnosis does indeed reduce the risk of sickness and death, and does not lead to other serious medical problems.

At the 8th International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention (IAS) in Vancouver, British Columbia, which ran from July 19 to 22, researchers presented numerous studies that added greater depth to the understanding of biomedical prevention’s potential, and also highlighted the challenges facing PrEP’s roll-out in particular.

To follow is a brief summary of various studies related to PrEP, HIV treatment as prevention (TasP), and early ARV treatment. Click the links for more detailed articles about any of the studies. For a full run-down of POZ reporting on studies presented at the conference, click here.

The START trial included 4,685 HIV-positive men and women who hadn’t taken ARVs yet and who had more than 500 CD4s at the outset. They were randomly assigned to go on treatment immediately or wait until their CD4s dropped to 350 or below, until they developed AIDS or other illnesses, or until they met qualifications for beginning ARVs according to guidelines in their home

country (35 nations were represented).

New results presented at the IAS conference showed that starting treatment early reduced the rate of serious AIDS-defining illnesses by 72 percent and serious non-AIDS illnesses by 39 percent.

The findings indicated that early treatment is safe. There was no difference between the two study arms in the rate of other potentially life-threatening health problems, as well as unscheduled hospitalizations for reasons outside of AIDS.

On the TasP front, the received wisdom has become all the more official: It is very difficult to transmit HIV with an undetectable viral load. The HPTN 052 study included 1,763 mixed-HIV-status straight couples from around the world. Running from 2005 to 2015, the study followed the couples for an impressive 9,822 person years. (Person-years refer to the cumulative time all participants have spent in a study. If 10 people spend an average of two years in a trial, this amounts to 20 person-years.)

Final results from the study, presented at the conference, showed that none of the HIV-positive partners who had an undetectable viral load transmitted the virus to their partner.

As for new information about PrEP, a bevy of studies addressed concerns about adherence to daily Truvada in the real world. Researchers are also exploring in greater depth the potential for success in non-daily dosing of PrEP.

Previous research among MSM has estimated that perfect PrEP adherence reduces the risk of acquiring HIV by at least 99 percent, possibly even 100 percent, and that taking as few as four tablets of Truvada each week still offers maximum protection. (This is known as medication "forgiveness.")

Numerous PrEP studies presented at the conference showed that high-risk participants did not take greater sexual risks after being given Truvada. (This does not imply that lower-risk people starting PrEP will necessarily follow a similar pattern.) There were few HIV transmissions among the major presented studies. Tests showed that those who did contract the virus had very little or no Truvada in their systems. More promising news was evidence suggesting that higher-risk participants were more likely to adhere to PrEP, underlining its potential for success in reducing HIV incidence.

In a study that tested PrEP in a real-world setting, MSM in San Francisco, Miami and Washington, DC, adhered well to daily Truvada. Sixty-three percent of the participants whose blood samples were tested had drug levels at all study visits suggesting that they were taking PrEP at least four days a week. Just 3 percent had drug levels at all study visits suggesting they were taking fewer than two pills each week, and 32 percent had an inconsistent pattern of adherence.

A similar study, this one focusing on MSM between the ages of 18 and 22, had disappointing results that suggested that using PrEP to fight the troublesome rates of HIV among this

demographic, particularly among young black MSM, may not lead to the kind of success that PrEP advocates are hoping for.

Initial adherence was good among the men, who received PrEP from clinics in 12 U.S. cities: Tests suggested that nearly 60 percent of them were taking Truvada four or more days a week. But after the third month of the trial adherence dropped off steadily and dramatically. By the end of the 48-week study, just 35 percent of the men took Truvada that often, and 30 percent were apparently not taking any PrEP. At that point, the median drug level among African-American participants was close to zero.

A trial of heterosexuals in Botswana offered considerable hope that rolling out PrEP in sub-Saharan Africa may take a bite out of the spread of HIV in that hardest-hit region. Tests taken every three months showed that the participants in the open-label extension phase of the TDF2 trial had detectable drug in their systems at an average of 93 percent of those study visits.

Finally, research of non-daily dosing of PrEP suggested that this may be a viable option for some. However, both MSM and women in one study had an easier time adhering to a daily regimen, at least on average. Additionally, Truvada taken intermittently appears to have greater power to protect against HIV acquisition through anal sex; vaginal protection remains uncertain.

The HPTN 067/ADAPT study included MSM and transgender women in Bangkok, Thailand, and Harlem, New York, and women in Cape Town, South Africa. Participants were randomly assigned to receive PrEP with instructions to follow one of three dosing protocols: daily; twice a week plus an extra dose following sex; or purely intercourse-based PrEP, with one dose up to 48 hours before anticipated sex and another two hours after sex.

In Bangkok, the daily, twice-weekly and intercourse-based dosing protected an estimated 85 percent, 79 percent and 65 percent of sexual acts, respectively. The corresponding respective rates for the Harlem group were 66 percent, 47 percent and 52 percent; and for the Cape Town participants the respective rates were 75 percent, 56 percent and 52 percent.

Researchers presented a substudy of the IPERGAY trial, which tested intercourse-based PrEP in French and Canadian MSM, as well data from research looking at Truvada metabolization. These study results provided conference-goers with details on the drug levels, as well as the corresponding risk reduction factors, achieved through intermittent Truvada use.

In the IPERGAY substudy, a double dose of Truvada, which participants were instructed to take two to 24 hours before sex, reduced the risk of infection by an estimated 40 percent if taken in isolation—not bookended by other doses. This underscored the importance of the trial's instructions to take one dose each day after sex, especially for men who do not already have Truvada in their systems before taking the pre-sex double dose.

The metabolization research found that levels of tenofovir, one of the two ARVs in Truvada, in cervical tissue cells only ever reached one-tenth the maximum level in rectal tissue cells. Top

levels in the rectum were reached after five days of daily Truvada, compared with 10 to 12 days in the cervix.

One, two and three daily doses of Truvada lead to a respective estimated 77 percent, 89 percent and 98 percent reduction in the risk of contracting HIV through anal sex. If someone takes Truvada daily for a month and then stops, the anal sex protection yielded from the drug remaining in the body one day and three, five and seven days later, is an estimated 97 percent, 96 percent, 93 percent and 90 percent, respectively.

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