

NEW PrEP HIV PREVENTION DATA AT IAS 2017

By Lynda Dee

The International AIDS Society (IAS) 9th Conference on HIV Science was held in Paris, France from July 23, 2017 thru July 26, 2017. The new data on PrEP is very exciting and continues to prove the effectiveness of PrEP in preventing HIV infection.

The latest Center for Disease Control (CDC) data presented tells us HIV infections in men who have sex with men (MSM) remains the highest risk category, representing 94% of new HIV infections in the US versus 62% in all other demographic categories. The Hispanic/Latino community's rates of new HIV infections is the highest risk category within the MSM population with 48% new infections versus 28% in other groups. New infections in people under 30 at diagnosis is 68% versus 41%. The percentage of new infections in MSM under 30 is 63% versus 31%. In Hispanic/Latino MSM, the rates of new infections are 32% versus 9%. These data make it obvious that we need enhanced prevention efforts in all MSM, especially Hispanic/Latino MSM and youth.

Gilead Sciences, the only company with an FDA approved drug for HIV prevention, Truvada for PrEP, reported on PrEP usage in the US. The CDC has informed us approximately 400,000 US MSM could benefit from PrEP. But according to Gilead data, only 120,000 MSM have started PrEP since 2012. This may be an underestimate since Gilead has no central data collection system for US PrEP usage, and this number only includes 80% of prescriptions. We all obviously need to do better in getting the word out of all MSM communities about the availability of PrEP to prevent HIV infection if they decide to use it.

There was an interesting study from the Boston Fenway Clinic that showed results from a national online survey of men over 18 years old who provided the reasons why they did not use PrEP. Fenway researchers found that cost and side effects were the main reasons for not using PrEP in men with more than a high school education and in men 30 or older. The ability to obtain PrEP was the main impediment to Black people and those not born in the US. Insurance concerns, side effect concerns, and not knowing how to access PrEP were also cited as well as a perceived lack of risk of infection in men in monogamous relationships. These data begin to help us to understand why people do not use PrEP, thereby

enabling us to do more targeted PrEP education in an effort to make PrEP more accessible for people who are interested in using it to prevent HIV infection.

New data from ongoing studies continues to show the sustained effectiveness of PrEP in preventing HIV infection. The initial one year PROUD study conducted in Great Britain found that PrEP was 86% effective in preventing HIV infection. Sixty percent of the original PROUD participants are still on PrEP 2-4 years later. Reduced rates of HIV transmission have been maintained in all participants who continued to use PrEP effectively, maintaining sufficient drug levels of PrEP. Doctors are able to tell for certain that PrEP continues to be effective and necessary because many participants experienced high rates of sexually transmitted infections (STIs) which means people are engaging in unprotected sex, but still not becoming HIV infected. All HIV infections in this study were the result of non-adherence to PrEP. So, the bottom line results from this study are that if you continue to take PrEP, you will continue to remain HIV negative. It should be noted that it is very important to maintain regular healthcare appointments in order to be tested and treated for any STIs.

The initial IPERGAY study conducted in France and Canada found that PrEP was 92% effective in preventing HIV infection in participants that used PrEP daily. Data presented at the IAS meeting showed that PrEP was even effective for those using PrEP “on demand” which means using a double dose of PrEP 24 hours before sex and a single dose for 2 days after sex. There were no HIV infections in those who remained PrEP adherent to this PrEP regimen. Although it may be easier to remember to take PrEP daily, PrEP “on demand” still may have public health significance. For example, approximately half of the people using PrEP in France take it “on demand”. This means the cost of PrEP is half the cost for half the people using PrEP in France.

HPTN 077, a study of ViiV’s long-acting cabotegravir administered by intramuscular (IM) injections (given in the buttocks) in 199 low risk participants in Brazil, Malawi, South Africa and the US for 41 weeks on study and with 52 weeks of follow-up after the study, showed that 600mg IM injections given every 8 weeks provided sufficient drug levels to protect against HIV infection in both men and women. Like long-acting studies for HIV treatment, oral dosing of cabotegravir is administered orally initially to ensure there are no serious side

effects. But only one drug seems to be effective for HIV prevention, unlike for HIV treatment which requires at least two drugs to effectively treat HIV.

Approximately 2/3 of HPTN 077 participants were women although participants in the US were mostly men. Only 8% of participants discontinued the study as a result of side effects, changes in risk behavior or pregnancy. Seventy-five percent of participants completed all study injections. While 34% of study participants experienced mild to moderate injection site reactions, 3/4 of them indicated that they would be willing to continue using the IM injections. Larger studies and a longer follow-up period will be necessary to confirm whether this dose will prevent HIV infection, but the initial results of long-acting cabotegravir IM injections for HIV prevention are very exciting.

Merck and Company has also been experimenting with Efdra, a new class of long-acting oral drugs for HIV prevention. Weekly doses of MK8591 are currently being studied in monkeys. There have been no HIV infections in the study arm receiving MK-8591 after 12 SHIV (HIV in monkeys) exposures. All the monkeys in the placebo arm (receiving no drug) became infected after 1-4 SHIV exposures. While we have a long way to go before this new class of drugs is widely available for people, it is exciting to know that we are on the way to also having long-acting oral drugs for HIV prevention. The goal is different prevention options for people with differing wants and needs. Like the many HIV treatment options available to people with HIV, it will be necessary to have a variety of prevention strategies to effectively prevent HIV infection.

There is also another very important prevention strategy that was presented at the IAS meeting, involving undetectable viral loads and the lack of risk of HIV transmission in discordant gay couples (one partner is HIV+ and the other is HIV-). In the group studied, there were 12,000 condomless male anal sex acts in 3/4 of the couples in this study. Approximately 3/4 of the positive participants were using HIV drugs throughout the study and had undetectable viral loads throughout the follow-up period. No HIV- partner became infected after condomless sex acts with an HIV+ partner who had an undetectable HIV viral load. None of the HIV- partners were using PrEP. These results confirm previous results in the PARTNER and Opposites Attract studies. Even the CDC now recognizes that condomless sex with an HIV+ partner who is undetectable is a

safe sex strategy. **CAUTION: Viral loads remain detectable in the first months after anti-HIV drugs are started. Be sure to use an effective HIV prevention strategy during this period.**

Anthony Fauci, Director of the NIH National Institute for Allergies and Infectious Diseases, said at an IAS press conference, "Scientists never like to use the word 'never' of a possible risk. But I think in this case we can say that the risk of transmission from an HIV-positive person who takes treatment and has an undetectable viral load may be so low as to be unmeasurable, and that's equivalent to saying they are uninfected. It's an unusual situation when the overwhelming evidence base in science allows us to be confident that what we are saying is fact."

This strategy is being widely championed by the Prevention Access Campaign with the tagline $U = U$ (Undetectable = Untransmittable) which is being spearheaded by Bruce Richman. $U = U$ is yet another exciting HIV prevention strategy in our HIV prevention tool box. Stay tuned for more new exciting HIV prevention news that will help you prevent the risk of HIV infection.