Not Drinking the PrEP Kool-AIDS

July 15, 2011 By Regan Hofmann

Wednesday, the Centers for Disease Control and Prevention (CDC) and the University of Washington released data gleaned from two African studies, namely "Partners PrEP" and "TDF2." The studies indicated that antiretroviral drugs (ARVs) taken daily by uninfected individuals--an approach known as PrEP, or pre-exposure prophylaxis--can reduce HIV acquisition through unprotected heterosexual sex by 62-73 percent, according to Partners PrEP, and nearly 63 percent, according to TDF2. The two drugs tested as PrEP were tenofovir (manufactured by Gilead Sciences and sold as Viread) and tenofovir plus emtricitabine (also manufactured by Gilead Sciences and sold as Truvada).

As the news came across the wires, widespread HIV/AIDS community support followed. AVAC, Project Inform, the San Francisco AIDS Foundation and many other advocacy groups as well as the leadership of the International AIDS Society heralded the results. Wednesday's PrEP lovefest mirrored the community's reaction to the results of "iPrEx" or the "Pre-exposure Prophylaxis Initiative," supported by the U.S. National Institutes of Health (NIH) and the Bill & Melinda Gates Foundation. The iPrEx results established that men who have sex with men and transgender women who take PrEP are, on average, 44 percent less likely to contract HIV; they were 73 percent less likely to do so if they took daily PrEP 90 percent of the time. It was also announced Wednesday that iPrEx will continue a placebo-less extension of the trial to study those who remained negative.

The results of Partners PrEP, TDF2 and iPrEx are critical indications that HIV can be successfully prevented with biomedical intervention--to a degree. But it is important to note PrEP offers various levels of reduced risk of HIV infection that are contingent on adherence. And that a range of 44-73 percent reduction in new HIV infection rates will not result in population level impact on the overall rate of new HIV infections. It's also important to keep in mind that a fourth clinical trial FEM-PrEP, failed to find any benefits among African women at risk for HIV. Therefore, PrEP should not be considered a prevention panacea but rather, a potential harm reduction strategy.

By comparison, consider the results of another recently completed treatment-as-prevention efficacy trial--a trial known as HPTN 052. The results from this trial were so compelling they were released by the HIV Prevention Trials Network in May 2011, years before results had been expected.HPTN 052 showed that when people living with HIV (the study consisted of primarily heterosexuals) were given ARVs and were sufficiently adherent to reduce their viral load to undetectable levels for a minimum of six months--there was a 96 percent reduction rate of HIV transmission to their HIV-negative sex partners. Now we're talking potential for population level

change.

Some groups cited PrEP's efficacy as critical proof that treatment as prevention works, leveraging that notion to further justify the need for universal access to treatment for people living with HIV. It's smart to leverage PrEP data as further proof that treatment can serve as prevention. Every additional piece of scientific evidence indicating treatment reduces the spread of HIV is further ammo in our fight against the virus. But frankly, the results of HPTN 052 offer sufficient, and arguably more compelling, justification for universal access to care. HPTN 052's results informed the new goal of putting 15 million people living with HIV/AIDS into care by 2015; a goal announced at the United Nations' high level meeting on HIV/AIDS this past June.

It must be acknowledged that treatment as prevention in people without HIV and treatment as prevention in people with HIV are very different things.

The results of HPTN 052 suggest that treatment may be a more effective form of prevention when given to people with HIV rather than to people who don't have the virus. Comparing the outcomes of the five aforementioned studies, it appears that administering ARVs to people with HIV rather than those without the virus offers a substantially higher rate of reduction in new HIV infections.

Treatment as prevention among people without HIV exposes healthy people to the side effects of drugs they don't have to take to stay well and survive. Treatment as prevention in people with HIV exposes people living with a disease to side effects of drugs that are, in most cases, necessary to prevent sickness and death. Obviously, we'd rather cure AIDS and should invest heavily to do so; until we have a cure, shouldn't we pursue a prevention path that has the upshot of keeping the people who are taking the drug alive as opposed to giving those drugs to people who don't need them for survival?

I think too many people have drunk the proverbial Kool-Aid on PrEP. Think about this:

Currently, there are 33.3 million people estimated to be living with HIV worldwide. To date, only 6 million of those people have access to ARVs. This means the bulk of the remaining 27.3 million people are headed toward near-certain death. Some of them quite rapidly.

HPTN 052 suggests that if we could achieve universal testing and access to care for all people living with HIV, we could reduce individual viral loads around the world and therefore lower the global "community viral load." By doing so, we could reduce the overall potential HIV transmission risk around the world significantly. If we could test and treat every positive person--and, admittedly, there are many significant issues to address in order to make universal access feasible, not the least of which is the challenge of paying for ARVs for tens of millions of people for the rest of their lives or until there is a cure--would we really need PrEP? Would we really need to give medications to people who don't have a disease?

I can hear the gasps already. (Especially from those who are funded to administer, study and sell PrEP...and those who manufacture and invest in it.)

But when you pit the prevention potential of universal access to care against the concept of PrEP, there seems no question to me about which approach is likely to save the most lives while preventing the most new cases of HIV most quickly and efficiently.

Therefore, especially in a time of limited resources, shouldn't we invest in a strategy that will save lives *and* stop the spread of AIDS *while* sparing healthy people the side effects of ARVs?

I want to be crystal clear: I support the notion of PrEP as a tactical tool for certain populations. All biomedical options that can work should be understood and added to the HIV prevention tool kit. We need every arrow possible in the quiver in our fight against AIDS.

PrEP could be a powerful form of harm reduction if made available to people most at risk for HIV, especially those who have no access to other forms of protection, like condoms and clean needles and injection equipment. PrEP could be helpful in situations in which condom negotiation is not possible, allowing PrEP to join the ranks of vaginal and rectal microbicides--other biomedical prevention tools being studied and developed. PrEP could be valuable for women who wish to conceive naturally and not risk contracting HIV. I would love to see PrEP adopted globally as part of a comprehensive prevention plan and given to people at high risk for HIV, who, again, are not able to get or use alternate tools, people like: sex workers; injection drug users; women and men in abusive relationships who don't have the power to advocate for their sexual health; and married people whose husbands and wives are being unfaithful and having unprotected sex.

But if we cannot find the political and financial capital to get ARVs to the 27.3 million people living with HIV who desperately want and need them, how are we going to secure the political and financial capital to get ARVs to millions of HIV-negative sex workers, drug users and other disenfranchised people in exceptionally compromised positions?

Unfortunately, PrEP will probably remain in the domain of the haves, not in that of the have-nots. Treatment as prevention is not going to be a reality for disenfranchised HIV-negative people at risk. PrEP will be for rich, HIV-negative people in the United States and other developed nations, gay and straight, who would rather take a pill and weather its side effects than use a condom.

PrEP is the viral equivalent of the birth control pill for people who can afford it. Price won't be an issue. To wit: Just before seeking FDA approval for Truvada as PrEP in April, Gilead jacked up the price of the drug by 7.9 percent.

I find it disconcerting that so many HIV treatment activists today, many of whom are living with HIV themselves, are wildly supportive of a prevention modality that has no benefit to people living with HIV other than arguably allowing HIV-positive people to have unprotected sex with HIV-negative people with a reduced risk of transmitting HIV, a risk that would be reduced further if the positive person was on treatment themselves. And especially when all activists could be advocating as vociferously for universal access to care for all people living with HIV; a prevention modality that has the added benefit of saving tens of millions of lives while stopping the spread of AIDS dead in its tracks.

The PrEP data has unleashed an ocean of press releases. I'd like to see the same volume of press releases come over the transom focused on issues like raising the U.S. debt ceiling, finding ADAP funding, protecting Medicaid and Medicare budgets, finding resources to implement the National HIVAIDS Strategy, supporting America's financial commitment to the President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis and Malaria and defending the perimeter of the Affordable Care Act.

Given the efficacy of treatment as prevention for people with HIV as established in the HPTN 052 study, I have to again ask: In a time of limited resources, how can we afford to invest in PrEP? Do we need to spend millions of dollars on drug trials and feasibility studies for PrEP? Wouldn't the world be better protected and more lives saved if that money instead was dedicated to increasing access to care for people with HIV?

Make no mistake: PrEP is a profit-driven sex toy for rich Westerners, disguised as a harm-reduction and prevention tool for disenfranchised people at risk for HIV.

And it's coming to a drugstore near you soon.

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