COMMUNITY HIV/AIDS CHAMP MOBILIZATION PROJECT

Prevention Research Advocacy Working Group (PRAWG)

Frequently Asked Questions about Pre-exposure Prophylaxis (PrEP)

(September 2008)

What is PrEP?

Pre-exposure prophylaxis (PrEP) refers to an experimental HIV-prevention strategy that would use antiretrovirals (ARVs) to protect HIV-negative people from HIV infection. In this experimental strategy, people take ARVs before they are exposed to HIV, with the goal of lowering their risk of infection. We need expanded options for individuals who cannot use or rely upon existing prevention tools like condoms or mutual monogamy between HIV-negative partners. PrEP is one of several HIV prevention strategies being tested in clinical trials today, and results from initial trials are expected over the next two years.

How does PrEP differ from PEP?

PEP, or post-exposure prophylaxis, is an HIV prevention strategy that uses a course of antiretroviral drugs which is thought to reduce the risk of HIV *after* events with high risk of exposure to HIV (e.g., unprotected anal or vaginal sex, needle stick pricks, or the sharing of needles.) Ideally PEP should begin within an hour of possible infection and no longer than 72 hours after exposure, whereas PrEP would be taken over time—either daily or intermittently—*before* high-risk exposure may take place.

Why is PrEP receiving more attention than other HIV prevention strategies?

PrEP advocates are **pro-HIV-prevention**, not solely pro-PrEP. It is critical that there is scale-up in the delivery of existing options while, simultaneously, there is development of new options. If it is shown to be effective, PrEP could be one strategy in a comprehensive prevention approach that includes an array of already proven methods such as male and female condoms, syringe exchange, male circumcision and PEP, as well as experimental methods such as vaccines and microbicides. Comprehensive prevention must also address the structural factors—such as lack of health care, marginalization, stigma and economic factors—that have hampered prevention efforts. Planning for potential integration of PrEP into HIV programming must be done in a way that furthers access to a full range of prevention options.

What is the rationale for PrEP research?

There is ample scientific reason to think that taking ARVs may help protect HIV-negative people from HIV infection:

- Studies done in non-human primates have found that pre-treatment with ARVs significantly reduces risk of infection by HIV-like viruses.
- Giving ARVs to HIV-positive pregnant mothers during labor and delivery, and to their newborn babies, both after delivery and during breastfeeding, has been shown to significantly reduce the likelihood of mother-to-child transmission of HIV.
- Though not definitive, studies of post-exposure prophylaxis (PEP) indicate that giving health care workers ARVs soon after occupational exposure to HIV may reduce the likelihood of infection.

What is the current status of the research?

There are currently five safety and efficacy trials looking at **daily dosing** of PrEP in different at-risk populations internationally: injection drug users (IDUs), heterosexuals at risk through sexual exposure, discordant heterosexual couples and gay men and other men who have sex with men (MSM). Two of the gay men/MSM trials are enrolling in the United States. Two additional effectiveness trials are being designed now and are likely to begin enrolling participants in the coming months. These trials are all testing either tenofovir (TDF) or a combination of tenofovir and emtricitabine (TDF/FTC). A list of current, planned and completed trials is available at http://www.prepwatch.org/pdf/Trials/PrEP_trials_table.pdf.

How is PrEP efficacy tested?
Trial volunteers are randomly assigned to either the experimental arm, which receives PrEP, or to the control arm. Both arms receive the same package of prevention counseling and services, which includes provision of condoms, treatment of sexually transmitted infections, and behavior change counseling. Clean needles and harm-reduction services should be provided in injection-drug user studies in order to meet basic ethical requirements. Volunteers are closely monitored for side effects associated with the medications. In order to get a clear picture of whether PrEP is a viable prevention strategy, data on safety and efficacy are needed on different populations: gay men and other men who have sex with men, injection-drug users, and heterosexual men and women.

Are gay men in the United States currently taking PrEP before its approval?
There have been reports of HIV-negative people taking ARVs for HIV prevention, despite the lack of trial results. However, several surveys by researchers have found very limited use, with most people surveyed not even aware of PrEP research or confusing it with PEP. If people are accessing ARVs from HIV positive friends or partners, it is likely they are not following the protocols of the research studies — which are looking at daily dosing—but may be taking it as they feel "it is needed." There is no data on humans on intermittent dosing of PrEP, though this may be studied in a next generation of trials.

Why is it urgent that PrEP advocates mobilize now?
By mid-2009, more people will be enrolling in PrEP trials than in all HIV vaccine and microbicide efficacy trials combined. At this time, however, there is no widespread, national dialogue about PrEP within and across key stakeholder groups. With multiple trials already underway, it is important that advocates and activists in the United States educate and engage stakeholders, including members of communities with high rates of HIV, prevention educators and service providers, public health workers, and public officials.

What is the PRAWG PrEP committee?
The PrEP Committee is a sub-group of the Prevention Research Advocacy Working Group (PRAWG) of the Community HIV/AIDS Mobilization Project (CHAMP). The Committee was founded in the spring of this year to form a US advocacy base around issues in PrEP research and to achieve a state of community preparedness defined by an understanding of basic facts of PrEP as a potential HIV prevention option, the relevant questions about safety and effectiveness, and the related challenges of implementation and financing.

Who are the PRAWG PrEP Committee members?
The PrEP Committee was founded by three HIV/AIDS community-based organizations: CHAMP, AVAC and Project Inform. They are seeking to expand its membership to the broader HIV/AIDS community as well as those working in family planning, STD control, IDU services and US health departments, among other relevant stakeholders. ***We welcome you to join us!***

Is the PRAWG PrEP Committee a project of Gilead, the company that makes the drugs that are currently being studied in the ongoing PrEP trials?
No. The PRAWG PrEP Committee is currently not funded by Gilead or any others. CHAMP, the sponsoring organization of the Prevention Research Advocacy Working Group does not accept pharmaceutical funds. The organizations that have come together to launch the PrEP committee have invested existing resources, and are now beginning to raise money to mobilize a base of community PrEP advocates.

Join the PrEP Committee of the CHAMP Prevention Research Advocacy Working Group (PRAWG). Contact Josh Thomas, at josh@champnetwork.org, or call 401-427-2302 x 30. For more information about PrEP, go to www.prepwatch.org.