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HIV Pre-Exposure Prophylaxis Medication: New Hope for Prevention Poses Important Questions

New research shows that anti-retroviral drugs, long used to treat people infected with HIV/AIDS, can also prevent at-risk individuals from being infected with the virus in the first place. The most recent trial results in the Pre-exposure Prophylaxis Initiative (iPrEx) represent a major breakthrough for HIV prevention, which has relied heavily on strategies to change behavior. HIV infects as many as 2.7 million people each year throughout the world.

According to the study published in the *New England Journal of Medicine* on November 23, 2010, high-risk populations who received a daily dose of Pre-exposure Prophylaxis (PrEP) on average reduced their incidence of HIV infection by 43%.

The issues discussed below will be the source of much debate as the federal government determines how to best craft HIV prevention policy in light of the new developments:

Potential Advantages of PrEP

- **Minimal side effects:** The drug prescribed during the trial, brand name Truvada, is already available to people with HIV infection and has been highly effective in increasing longevity and quality of life for people with HIV/AIDS. Truvada was approved for use in 2004, and more than one million HIV-infected people around the world have now used this drug. As a treatment, Truvada has been shown to be safe with minimal side effects. PrEx participants had comparable experiences: the group assigned to receive the drug as prophylaxis

reported only mild side effects such as nausea when compared with the placebo group.

- **Convenience:** Truvada stands out among the many anti-retrovirals as one of the most convenient to use. Truvada is a combination pill, which only needs to be taken once a day and can be taken with or without food. Given that HIV-negative individuals are otherwise healthy, the fact that Truvada is relatively safe and easy to use will be advantageous when individuals decide whether or not to take a daily medication to prevent a disease they do not have.
- **Effectiveness:** PrEP may be an effective HIV prevention tool for high-risk individuals. Although PrEP's efficacy rate of 43% may seem low in comparison with the efficacy rate of 98% associated with condom use, many factors may influence these numbers. The effectiveness of PrEP depends largely on how consistently the individual takes the daily pill; for those with higher adherence to the regimen, the reduction in risk of HIV infection increased to 73%. Similarly, condom effectiveness depends on correct and consistent use. Condoms used incorrectly may slip or break and if they are not used during each and every sex act, efficacy may drop to 85%. The efficacy of PrEP could increase because people can take a daily pill without informing their partners. The efficacy of condoms is reduced by the need to negotiate use with each sex partner and with each sex act.

The drug prescribed during the trial is already available to people with HIV infection and has been highly effective in increasing longevity and quality of life for people with HIV/AIDS. Its efficacy rate in HIV prevention ranges from 43% - 73%, depending upon adherence to the treatment regimen.

Behavioral considerations may provide the greatest challenge to using prophylaxis medication as tool to prevent HIV, however the study suggests that when these medications were used in conjunction with prevention services, participants reduced risk behaviors, reporting decreased sex partners and increased condom use.

Disadvantages/Potential Obstacles to the Widespread Use of PrEP

- Development of drug resistance: One of the primary concerns with the widespread prescribing of anti-retrovirals is that the HIV virus will evolve and become resistant to that particular medication. Once drug resistance emerges, the current medication will cease to be effective, subsequent medications may be less effective, and attempts to counter drug resistance may lead to more complex, expensive, and toxic regimens. An important consideration when prescribing PrEP to HIV-negative persons is that if they become infected with HIV, they may already have developed drug resistance to Truvada. As the proportion of individuals infected with a Truvada-resistant strain of HIV grows, this drug will become less effective as a tool for prevention and treatment. During the 14-month iPrEx study, none of the individuals who became infected with HIV had developed drug resistance; however, this finding may be a result of the relatively short study period.
- Serious health side effects: Daily dosage of anti-retroviral medication taken for preventative measures may cause serious health problems in otherwise healthy people. The side effects associated with Truvada range from mild nausea to potentially life-threatening complications such as kidney failure. Although no severe adverse events could be attributed to PrEP in the iPrEx study, the consequences of taking such toxic medication may emerge with time.
- Health behavior issues: In addition to these medical concerns, behavioral considerations may provide the greatest challenge to using PrEP as tool to prevent HIV. It is feared that individuals taking PrEP may gain a false sense of security or “perceived immunity” against HIV, which could lead to increased risk behaviors. The PrEx study measured the effects of PrEP when administered together with the current gold standard of prevention measures: risk-reduction counseling, condom distribution, regular HIV testing, and clinical care for other STIs. Particularly if PrEP is made available where these prevention services are lacking, it is feared that people may have more unprotected sex, which would also reduce the efficacy of the medication and ultimately result in more HIV infections. The evidence from the iPrEx study suggests, however, that when PrEP was provided in conjunction with prevention services, participants reduced risk behaviors, reporting decreased sex partners and increased condom use.

Costs of PrEP

While the costs for providing PrEP are rather significant, there are longer-term substantial savings that would be associated with providing it, so the costs cannot be considered solely a disadvantage or obstacle. Preliminary annual costs for PrEP have been estimated at \$14,400 per year. This figure varies depending upon the source paying

for the drug and the costs of attendant services, including regular HIV testing, ongoing blood work to monitor possible side effects, and risk-reduction counseling.

Many argue that the prescription of Truvada to HIV-negative individuals is highly cost effective when compared with providing more complex treatment regimens to persons diagnosed with HIV/AIDS. When HIV progresses to AIDS, the annual cost of anti-retroviral treatment can be as much as \$24,000 a year. Hospital care to treat secondary illnesses and complications can add another \$7,800 per year.

Providing PrEP can be considered on a yearly basis, rather than a multi-year or lifetime cost, since it can be discontinued at any time. If high-risk behaviors such as having unprotected sex and/or exchanging sex for drugs or money are reduced over time, the medication may no longer be needed, and thus the costs of the preventive treatment would cease. In comparison, once HIV-positive individuals progress to an AIDS diagnosis and a prescription of anti-retrovirals is necessary to keep alive, they will be required to follow a daily medication regimen for the remainder of their lives. Due to the efficacy of these anti-retrovirals, individuals with HIV/AIDS are living longer, healthier lives than ever before with life expectancy similar to that of HIV-negative persons. Hence, the over \$30,000 yearly cost estimate of treating people with AIDS needs to be considered for at least a duration of one to ten years in the United States, if not longer

This Policy Rx is a joint effort of the CDPH STI/HIV/AIDS Division and the CDPH Office of Policy and Planning.