

Understanding the implementation of Pre-Exposure Prophylaxis (PrEP) to prevent HIV in California

Objective: Scientists announced the results of the iPrex trial in November 2010, showing that overall, a daily dose of Truvada, a combination of two oral antiretroviral drugs, tenofovir disoproxil fumarate and emtricitabine, reduced HIV infection in a sample of high-risk men who have sex with men (MSM) and transgender (TG) women by 44 percent. Among those study participants who took Truvada 90 percent of the time, the effect increased to a 73 percent reduction in new infections.

While these findings are significant, and have implications for the HIV prevention arena, it is unclear how the trial results will be understood and implemented among medical providers serving MSM and TG communities and MSM and TG individuals who may seek out PrEP.

This is a study to examine the acceptability of PrEP among medical providers and high risk MSM and TG women who may be candidates for this form of HIV prevention. In addition, this study would also model the cost effectiveness of providing PrEP to high-risk MSM and TG on the HIV epidemic in California, and would compare the results of the analysis to the epidemic impact of Testing and Linkage to Care (TLC+) prevention programming.

Methods: We will purposively recruit 30 medical providers in San Francisco, Alameda, and Los Angeles counties to

Questions:

1) *How do providers approach managing patients who want to use PrEP?*

2) *What are the perspectives of high risk people PrEP as an HIV prevention strategy?*

3) *What is the potential impact and cost of implementing PrEP?*

4) *As a prevention strategy, how does PrEP compare to TLC+?*

participate in semi-structured, in-depth interviews. We will recruit internal medicine providers who specialize in or have a professional reputation for HIV treatment, and who have a significant proportion of MSM and/or TG people in their patient populations. Interview topics for medical providers will include: assessing clinician impressions of PrEP and the CDC guidelines, considerations of cost, the capacity of primary care practices to complete necessary billing and follow-up care, thoughts about dosing schedules, and following patients regularly over long periods of time.

In addition, we will purposively recruit up to 30 MSM and TG community members from San Francisco, Alameda, and Los Angeles Counties, sampling for diversity among participants with respect to age, race/ethnicity, income/education level, employment status, and medical insurance status. Interview topics for MSM/TG participants will include: a personal risk assessment for HIV, willingness to take a pill on a daily basis, ability to follow adherence demands and regular check-ups, levels of acceptable side effects and potential long-term physical risk, willingness to self pay and cost considerations, decision making around starting and stopping PrEP, and the perceived benefits of using PrEP, particularly in conjunction with other HIV prevention modalities (ie, condom use).

Activities: We currently have an application outlining the study objectives and methods under review at the UCSF Committee on Human Research. We plan to begin recruitment in the early Spring of 2011, and will begin collecting data as soon as we receive approval.

We hope the answers to these questions will assist in the ongoing implementation work being undertaken by various groups in California. The study will be completed by Fall 2011.

