

Multimodal Interventions to Improve Adherence to Oral Tenofovir/Emtricitabine as Pre-Exposure Prophylaxis in Women in Southern California

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PrEP Demonstration Research Project Supplement
Awarded: 2015

Daily oral pre-exposure prophylaxis (PrEP) with tenofovir/emtricitabine (TDF/FTC) as part of a combination prevention package has been shown to be effective for HIV prevention in randomized control trials of MSM and heterosexual men and women at risk for HIV infection; however, some studies in African women have shown lack of efficacy that is believed to be in large part due to inadequate PrEP adherence. In addition, pharmacokinetic studies in women suggest that near-perfect adherence for TDF/FTC oral dosing may be more critical for protection against vaginal compared to rectal exposures. Taken together, these results imply that women may require substantially greater levels of adherence to oral TDF/FTC to effectively decrease HIV acquisition. Therefore, interventions to optimize adherence are particularly vital to maximizing the protective efficacy of PrEP for women. Although current FDA approval and CDC clinical guidelines for oral TDF/FTC as PrEP include at-risk women as candidates for use, limited clinical data exists on the use of PrEP in US women. Further research is needed to advance effective implementation, particularly taking into account the known challenges to achieving and maintaining high levels of adherence for women.

In this demonstration project, we will evaluate adherence to, and acceptability of once-daily oral TDF/FTC as PrEP among HIV-uninfected women in Southern California who are at increased risk of HIV acquisition. Los Angeles and San Diego represent two of the top three counties in California of number of reported HIV/AIDS cases. In combination, they total over half of the number of HIV cases in the state supporting the need for ongoing prevention efforts in all at-risk populations (1). Working in tandem, the LAC PATH and CCTG partnership provides a unique opportunity to further collaborative research that has been fostered within the CHRP funding structure, capitalizing on the strengths of existing individual projects in MSM and transgender women.

Each group will plan to enroll 50 women, for a total of 100 participants across five clinical sites in Los Angeles and San Diego counties. The proposed clinical sites currently provide services to a racially and ethnically diverse population and will enable outreach to potential female participants disproportionately affected by the HIV/AIDS epidemic, with a focus on African American and Latino women. Given the centrality of adherence to PrEP efficacy in women, we will implement a multi-modal, intensive adherence strategy to support PrEP delivery that will innovatively combine the use of technology, therapeutic drug monitoring and behavioral counseling.

Findings from this study will allow us to better understand those women that are most likely to initiate and adhere to PrEP as well as the effectiveness of a combination intervention for supporting adherence in this unique group. By exploring motivations for PrEP use and characterizing adherence patterns, behaviors, acceptability, safety and fertility goals in women, we aim to expand the data set of oral TDF/FTC as PrEP in women to include US-based women and help inform decisions and policy around further implementation and scale up.