

CHRP launches initiative to evaluate the HIV prevention pill among California women

The [California HIV/AIDS Research Program](#) (CHRP) of the University of California announced on November 4, 2015 that it awarded grants totaling \$2.2 million to two teams of investigators to provide and evaluate the HIV prevention pill, commonly called “PrEP” (Pre-Exposure Prophylaxis), among women who are HIV-negative and at risk of becoming infected with HIV.

Over the next two years, research teams in Los Angeles, San Diego and the San Francisco Bay Area will offer PrEP to an estimated 150 women at risk of HIV infection. Researchers will design and implement unique and targeted interventions to increase access, uptake and adherence to medication for these women.

In these California demonstration projects, PrEP will be delivered as part of a comprehensive prevention package including risk reduction counseling, sexually transmitted infection screening, and other components. Gilead Sciences, Inc. of Foster City, CA will provide the HIV prevention pill (Truvada®) to support these demonstration projects.

Since the approval of PrEP there have been demonstration projects in the United States, but most of these have focused on enrolling men who have sex with men (MSM). While these projects have provided valuable information about PrEP uptake, adherence, and outcomes in MSM, data on PrEP use and implementation in women within the U.S. is lacking. Women who are candidates for PrEP face a unique set of issues. For example, research has indicated that compared to men, women taking PrEP may have less margin for forgiveness for missing doses to obtain similar levels of effectiveness in preventing HIV. By launching the first PrEP demonstration project initiative in the U.S. to focus exclusively on women, CHRP will help to fill this gap in knowledge. “These studies will provide critical information on the implementation of PrEP among women in California, and will help guide state and national efforts to address the epidemic in this population,” said George Lemp, Dr.P.H., director of the University of California-based CHRP. “We hope funding a project that focuses on the unique issues facing women will provide knowledge to help increase access to and acceptance of PrEP in this population, and help to curtail the epidemic in this state,” Lemp said.

The two funded grantees for this initiative include:

[UCLA, UCSD](#) and [The Division of HIV and STD Programs at the Los Angeles County Department of Public Health](#), (Lead Project Investigators, Dr. Raphael J. Landovitz and Dr. Sheldon Morris) in collaboration with several community-based organizations in both San Diego and Los Angeles, including [AIDS Project Los Angeles](#), [Christie’s Place](#) in San Diego, and [Altamed](#) (total 2-year budget = \$1.5 million).

These researchers will evaluate adherence, acceptability, and outcomes of PrEP implementation 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 with regard to number of reported HIV/AIDS cases. The Southern California grantees will enroll a total of 100 participants across four clinical sites in Los Angeles and San Diego counties. The 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 as an issue impacting PrEP efficacy in women, the grantees plan to 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. “This is a tremendous opportunity to study how we can reach women at risk for HIV infection who need PrEP and then optimize their adherence,” said Dr. Sheldon Morris, one of the Principal Investigators on the study. Another Principal Investigator, Dr. Raphael Landovitz agrees, “We are tremendously excited to build on the ongoing partnerships we have with CHRP and our community partners. With this project, we are building on our expertise in PrEP for MSM by specifically designing a novel delivery package for women – including HIV-uninfected women who may be interested in a pregnancy with an HIV-infected male partner,” Landovitz stated.

The [Center for AIDS Prevention Studies](#) at UCSF (Lead Project Investigator, Dr. Janet Myers) and The [East Bay AIDS Center](#) at Alta Bates/Summit Medical Center in Oakland and Berkeley (Lead Project Investigator, Dr. Jeffrey Burack), in collaboration with the community health center, [LifeLong Medical Care](#), with locations in Oakland and Berkeley (Co-Investigator, Dr. Frances Herb). (total 2-year budget = \$750,000).

This group of grantees will offer women access to PrEP at LifeLong’s primary care clinic in East Oakland, an ethnically diverse, economically depressed geographic area with a high prevalence of HIV. Later in the study, they will provide PrEP access to women seen at one of Lifelong Medical Care’s Berkeley locations. They will study whether women seen in these primary care settings are interested in and willing to use PrEP as a prevention strategy by providing access to PrEP to 50 women and following them over a 15-month period. The PrEP package they will offer to enrollees includes free access to PrEP, regular HIV screening, STI screening and treatment, family planning, contraception, and sexual health promotion counseling, as well as a series of screenings and referrals related to mental health, substance misuse, and domestic violence. The researchers will also assess whether the availability of PrEP draws women who otherwise would not seek sexual and other health services in a primary care setting. “We are so excited to be working with our community health center partner – LifeLong Medical Care – because their clinics have not traditionally been seen as ‘HIV’ settings. We will be providing new access to the best HIV prevention tools available to women who are vulnerable to HIV,” said the study’s Principal Investigator, Dr. Janet Myers. Her collaborator at the LifeLong clinics, Dr. Frances Herb, points out the importance of focusing HIV prevention efforts on women, “In my years caring for people infected with HIV, women are far more likely than men to be shocked with disbelief if they are told that they have been infected with HIV. Forty-five years after the first edition of ‘Our Bodies Ourselves’, women are better informed and more empowered around protecting their sexual health. But in the United States, we still think of HIV as being an epidemic that primarily affects gay men,” said Dr. Herb.

The California HIV/AIDS Research Program (CHRP) fosters outstanding and innovative research that responds to the needs of all people of California, especially those who are often under served, by accelerating progress in prevention, education, care, treatment, and a cure for HIV/AIDS. CHRP was founded by the California state legislature in 1983 to respond to the HIV/AIDS crisis in the state. Since the program began, CHRP has funded more than 2,000 research projects and distributed and monitored more than \$275 million in state funds for HIV/AIDS research.