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Press release and ***complete feature-length article*** available at www.californiaaidsresearch.org

An HIV Prevention Pill for Transgender Persons:

UC launches first in the nation demonstration project

The California HIV/AIDS Research Program (CHRP) of the University of California today (April 25th) announced that it has awarded grants totaling \$9.4 million to three teams of investigators to provide and evaluate PrEP, the HIV prevention pill, among transgender persons at risk for HIV acquisition in California. This is the first PrEP demonstration project in the U.S. to focus exclusively on transgender persons.

Three research teams, one in San Diego and Los Angeles and two in the San Francisco Bay Area will offer PrEP to an estimated 700 transgender women and men, with a special focus on transgender persons of color, over the next four years. Researchers will design and implement unique and targeted interventions to increase access, uptake, and adherence in the transgender community. As part of this work, the research team will also investigate potential drug interactions between PrEP and hormone use.

Transgender persons are extremely vulnerable to HIV infection. By some estimates transgender women are up to 50 times more likely to be infected with HIV compared with other adults, and efforts are needed to deliver effective prevention services to this population. Transgender persons of color have been particularly impacted by HIV. While previous PrEP demonstration projects have focused on men who have sex with men, data on PrEP use and implementation with the transgender community is lacking.

Transgender populations face a number of HIV prevention challenges including sociocultural, economic and health-related factors. Some of the barriers include stigma and transphobia, lack of protections against discrimination, trauma, violence, substance use and poor mental health, sex work, incarceration, homelessness, unemployment, and limited access to trans-friendly health care. While some work has been done in an effort to address these challenges, more is needed, including efforts that not only tackle these underlying drivers of risk but that also employ recent advances in the biomedical prevention of HIV.

The limited research that has been conducted to date suggests that compared to cisgender men (men

who were assigned male sex at birth and who also identify as male), transgender persons taking PrEP may face additional barriers to adherence, especially for those who are most at risk of acquiring HIV. Transwomen have expressed concerns about potential interactions between PrEP and hormone therapy, which could impact adherence. While drug interactions are not expected between these medications, it will be important to confirm that the use of one does not impact the effectiveness of the other. By launching the first of its kind PrEP demonstration project initiative focused on transgender people, CHRP will help to address barriers to PrEP in the transgender population. “These studies will provide critical information on the implementation of PrEP among transgender people in California, and will help guide state and national efforts to address the epidemic in this often neglected population at high risk for HIV,” said George Lemp, Dr.P.H., director of the UC-based CHRP. “We hope funding a project that focuses on the issues facing transgender people will provide knowledge to help increase access to and uptake of PrEP in this population, and ultimately help to curtail the epidemic in this state,” Lemp said.

In these 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.

The three funded grantees for this initiative include:

- **Team 1: The University of California, San Diego, The Los Angeles LGBT Center, and Family Health Centers of San Diego, (Lead Project Investigators Dr. Sheldon Morris, Dr. Robert Bolan, and Dr. Christian Ramers). The team is also collaborating with USC and Harbor-UCLA (total 4-year budget = \$3.75 million).**

These researchers will test if a transgender-focused case management approach to contextualize PrEP within the needs of the whole person can improve PrEP linkage and engagement in the transgender population. Furthermore, the researchers plan to use an already developed personalized text messaging reminder system and will test if adding real-time counseling at times of missed doses will improve overall success in taking regular dosing over the course of study. Both of these interventions were consciously designed to be practical additions to current clinical care.

The team will also examine possible drug interactions between PrEP use and feminizing hormones by using the daily reporting of doses taken by text messaging to confirm whether the same drug levels expected to be protective for HIV are achieved by transgender women on hormonal therapy, and if taking PrEP is associated with any changes in hormone levels. “This is truly an exciting opportunity to advance HIV prevention in transgender individuals with a high level of scientific rigor. It will be a privilege to work with the CHRP, the collaborating sites and, most of all, the deserving transgender community,” noted Dr. Sheldon Morris, the UCSD-based principal investigator.

- **Team 2: University of California, San Francisco (Principal Investigator: Jae Sevelius, PhD, Co-Principal Investigator: Madeline Deutsch, MD, MPH), The Gladstone Institutes (Co-Principal Investigator Robert Grant, MD), The Gender Health Center in Sacramento (Co-Investigator:**

Ben Hudson) and La Clinica de la Raza in Oakland (Co-Investigator: Leyla Welborn, RN, MS, FNP) (total 4-year budget = \$2.9 Million).

This research team will develop and evaluate “Trans Research-Informed communities United in Mobilization for the Prevention of HIV (TRIUMPH)”, a culturally-relevant, community-led PrEP demonstration project, driven by the needs and experiences of transgender women of color. The TRIUMPH uptake intervention consists of community-led mobilization efforts to increase knowledge and acceptability of PrEP, utilizing PrEP champions from within trans communities, and trans-specific PrEP educational materials, including trans-specific patient decision aids that will assist people in making informed choices about PrEP.

To improve adherence the team is planning an intervention consisting of peer-led health workshops and one-on-one personalized adherence counseling sessions. The team is also planning a pharmacokinetic sub-study that will investigate potential drug interactions between PrEP and hormone use. This research will answer important questions about how the proposed interventions affect people’s choices about whether or not to take PrEP (uptake), whether they take it as prescribed (adherence), whether PrEP works well for participants (effectiveness), and whether they continue to take PrEP for the duration of the study (persistence).

Dr. Jae Sevelius, the study’s Principal Investigator commented, “Our team has been conducting community-based research with trans communities across California and beyond for more than a decade, including behavioral HIV prevention intervention development for transgender women of color. The HIV-related disparities experienced by trans women have been exacerbated by the ongoing aggregation of trans women with MSM and the persistence of inadequate prevention approaches adapted from MSM strategies without knowledge or consideration of trans women’s unique sociocultural context. We applaud CHRP in their leadership in addressing PrEP implementation questions, and we believe these efforts will result in an unprecedented and highly valuable contribution to the field of HIV prevention among transgender communities.”

- **Team 3: The San Francisco Department of Public Health Population Health Division (Lead Project Investigators: Albert Liu, MD, MPH and Erin Wilson, DrPH), Tom Waddell Urban Health Center (Co-Investigator: Royce Lin, MD), Castro Mission Health Center (Chris Nguyen, MD), Asian Pacific Islander Wellness Center (Co-Investigator: Tri Do, MD, MPH) and Tri City Health Center in Fremont (Co-Investigator: Zettie Page, MD, PhD) (total 4-year budget = \$2.6 Million).**

This research team plans to use a Patient Centered Medical Home approach to develop and evaluate a comprehensive PrEP education, access, and support package for HIV negative transwomen and transmen in the San Francisco Bay Area (SFBA). The team is planning a broad, trans-specific social marketing campaign to increase knowledge about PrEP, and will collaborate with highly experienced staff to integrate PrEP delivery and support into four of the largest trans-specific clinics in the SFBA that provide culturally-competent care, including hormone provision. Specifically, their proposed interventions include a sexual risk assessment tool, online education, SMS-based adherence

reminders/support, panel management and peer navigators.

The research will determine the acceptability of the tools, PrEP uptake and adherence, most useful support strategies, and measure any social harms and benefits of PrEP use. The team will also investigate potential drug interactions between PrEP and hormone use. The long-term goal of the project is to develop a successful PrEP delivery and support model that can be scaled up to increase PrEP uptake and adherence among at-risk transgender women and men in California and the US.

“This is a tremendous opportunity to expand PrEP access and support in the transgender community. We commend CHRP’s leadership in addressing this prevention gap and look forward to working closely with the transgender community in developing and implementing this project,” said Dr. Al Liu, the study’s principal investigator.

Dr. Tri Do, the Chief Medical Officer at the Asian & Pacific Islander Wellness Center also commented, “these projects have the potential to fill an unmet scientific and public health need,” remarked Do. “More critically, the transgender community may finally get to see healthcare equity when it comes to new HIV infections.”

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CHRP was founded by the California state legislature in 1983 to respond to the growing 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.

For more information about the California HIV/AIDS Research Program, please visit:

<http://www.californiaaidsresearch.org/>