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Contact: Dr. Lisa Loeb Stanga, California HIV/AIDS Research Program at UC Office of the President
Phone (510) 587- 6041, Fax (510) 587-6325, email lisa.loeb.stanga@ucop.edu

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

Including Robyn: Does HIV PrEP Help Transgender People?

UC launches first culturally-appropriate PrEP demonstration project in the U.S.

Robyn Learned doesn't see faces like hers in HIV prevention outreach campaigns, which favor handsome young men playing guitar, drinking wine, and posing in snow-capped mountain landscapes.

Transgender, Robyn is part of a community that has been tragically excluded from the national crusade to protect people from HIV, the virus that causes AIDS.

"It's hard getting people to even acknowledge that there's a problem - because there's no one keeping track," said Learned, 49, an HIV counselor at Sacramento's Gender Health Center.

That will change this April with the launch of the nation's first-ever transgender-focused research initiative to test, evaluate interest in, and measure utilization of the HIV prevention pill, an anti-retroviral preventive approach called PrEP, short for pre-exposure prophylaxis.

If successful, the \$9.4 million California HIV/AIDS Research Program-funded project could help reverse a frightening trend that is devastating the lives of people already struggling with elevated rates of extreme poverty, homelessness, intimate partner violence, attempted suicide, substance abuse, and incarceration.

While PrEP is becoming a routine part of daily life in urban communities of men who have sex with men, it remains unknown or underused among transgender people - especially women.

The consequences are deadly: a stunning 40 percent of transgender women are living with HIV, according to Dr. Erin Wilson, a research scientist in the HIV Epidemiology Section of the San Francisco Department of Public Health, and one of few HIV researchers with expertise in transgender care.

Rates among African American and Latino transgender women are even higher, she said.

"They are at great risk," said Laura Packel, program officer at the California HIV/AIDS Research Program (CHRP), housed at the University of California Office of the President, which is overseeing the research. "HIV is a huge problem in the transgender community, with a prevalence that is many, many times greater than all other populations."

The CHRP effort, the first and only one of its kind in the nation, will enroll a total of 700 transgender participants in three distinct research studies. Of these, at least 40 percent will be persons of color; 20 percent will be African-American.

Geographically dispersed, the three studies aim to reach people in northern and southern California over a four-year period. The two Northern California grants – one based at UC San Francisco and the other at the San Francisco Department of Public Health - will involve clinics in Oakland, Fremont, Sacramento, and San Francisco. The third grant, based at UC San Diego, will work with clinics in Los Angeles and San Diego.

While each takes a different approach, they complement each other, said Packel. "With so many people enrolled, there will be enough scientific rigor and statistical power that we can make a statement about how to improve PrEP uptake, adherence and effectiveness in transgender populations," she said.

The teams also will investigate drug levels in patients over time, to detect any interactions between PrEP and hormone treatments, said Dr. Albert Liu, co-investigator of the San Francisco Department of Public Health project. While unlikely, "it is important to confirm that there is or is not an interaction, with a thorough drug study," he said.

Previous research has failed to answer a key question: Does PrEP help transgender people? These earlier studies targeted men who have sex with men - and lumped transgender people together with those men, even though the two groups have very different needs.

"They were treated like an afterthought," Packel said.

There were other problems, as well. The gender characteristics of study participants were not accurately assigned, which contributed to a shortage of transgender people enrolled, said investigator Dr. Sheldon Morris of the Antiviral Research Center at UC San Diego. Transgender people were leery of participating. And many dropped out.

Furthermore, hidden within these large previous studies was a puzzling finding: Transgender people on PrEP tended to have lower drug levels in their bodies than the men who have sex with men did. This is perilous, increasing the risk that HIV could gain a foothold, and become resistant to treatment. There may be issues specific to the transgender population that make adherence more difficult, or there may be a biological cause behind this finding – determining the underlying cause is extremely important.

"What that told us was that transgender people deserved a specific demonstration project to look at how to reduce HIV risk for them," said Jae Sevelius, who is leading the UCSF Project.

"What do transgender women really need?" she asked. "By funding these trans-specific projects, CHRP is the leading edge of what needs to happen."

The medical community "has fallen way behind in understanding their unique needs," she said.

Finding and educating the transgender population is the first challenge.

They are largely unaware of PrEP, because it has been marketed as a men's intervention, said Liu, clinical research director of "Bridge HIV" at the San Francisco Department of Public Health.

And the transgender community lacks some of the social cohesion that makes outreach so easy in the gay community. They tend to be more isolated. And they're diverse. Transgender refers to people whose identity does not conform to gender based on biological sex, external characteristics or sex assigned at birth. It includes people who self-identify as male-to-female, or transgender women; female-to-male, or transgender men; or "two spirited."

"When you talk about reaching people at high risk for HIV, it's pretty easy to find the males out there," said Learned. "With transgenders, it's a whole different thing," she said.

There's a further complication: Sexual behavior isn't based on gender identity. Someone may identify as both transgender and either heterosexual, gay, bisexual, or lesbian. A transgender person may have a partner who is male, female, or transgender themselves.

"You can't assume they're at high risk," said Learned. "The only way to find out is to ask them."

That's a tough conversation. They may not reveal they are transgender due to distrust and fear of discrimination.

Furthermore, HIV prevention may not be a major priority in their lives, the researchers agreed.

Studies show that many have traveled a rocky path in life, facing stress, discrimination, poverty, and violence. Some have been sexually abused as children. As adults, they report being physically assaulted in trains and buses, retail stores, and restaurants. Others are victims of violence at the hands of their partners.

After being called "sissy" and harassed at school, they're more likely to drop out before finishing high school or earning a degree, said Sevelius, a licensed clinical psychologist and assistant professor with the Center for AIDS Prevention Studies at UCSF's Department of Medicine. So they're less able to secure a steady job, and earn a dependable income. They may not be able

to afford reliable transportation and may face discrimination when seeking housing. Family disapproval and confusion can create a burden of stress and estrangement.

In research conducted in San Francisco, transgender people were more likely than gay or straight men to live in transient housing and to be less educated. Struggling, they may pursue high-risk activities, such as hustling sex work, to meet their basic survival needs.

They may resort to alcohol and drugs to cope. And they experience higher rates of mental illness. These problems can land them in prison - trapping them in an escalating cycle of poverty, unemployment, and homelessness.

Even if offered PrEP, such turbulence also makes it hard to consistently take a prevention drug, according to the researchers.

"There is a hierarchy of needs. If people don't have a job, don't have steady income, and don't have a place to put their head at night, then thinking about daily medicine is challenging," said Dr. Wilson, co-investigator of the San Francisco Department of Health project.

A New York City study found that among newly diagnosed HIV-positive transgender women, 51 percent had substance use, commercial sex work, homelessness, incarceration, and/or sexual abuse problems - compared to 31 percent of other newly diagnosed people who were not transgender.

"The real upstream root of this is social marginalization," Sevelius said. "Transgenders experience a lot more instability in their lives due to the marginalization they experience."

"We can't directly address the social marginalization," she said. "But we can give people a means of coping, a safe place to get health care and social support."

The three new research projects are creating strategies to tackle these unique challenges.

Researchers know that transgender people are less likely to come looking for them. So they are reaching out to community clinics with deep-rooted relationships and extensive experience in transgender care.

By connecting with community groups, "we can work on practical solutions," said UC San Diego's Morris.

The teams will also strive for efficiency and economy - making it possible, for instance, for participants to get both hormones and PrEP from the same provider. By minimizing appointments, they hope to boost participation.

"They prioritize their hormone therapies, so we need to leverage those priorities, as well as minimize the need for them to run around," said UCSF's Sevelius.

The three teams also will monitor whether PrEP drug levels are affected by hormones, asking: do hormones impair the protective properties of the drug? Or - vice versa - does PrEP interfere with hormones?

In the San Francisco Bay Area, Liu and Wilson's project will work with four clinics: "Transgender Tuesdays," a program at Tom Waddell Urban Health Care; "Dimensions," for transgender youth at Castro Mission Health Care; the Asian Pacific Island Wellness Center in San Francisco; and the Tri-City Health Center in Fremont.

They will enlist transgender "peer navigators" to help recruit and link people to PrEP at the clinics. These "navigators" will also educate and emotionally support participants, as well as help them negotiate insurance issues, said Liu.

Transgender-specific educational materials will be designed to address their common concerns, such as side effects.

A "speakers bureau" will feature well-known leaders in the transgender community, who can describe the role of PrEP in HIV prevention. These speakers also will describe personal stories about PrEP use, such as how to explain to a partner that you're taking a pill for prevention.

In addition, there will be a social marketing campaign - using posters, palm cards, and websites - designed with input from an advisory board of transgender people, Liu and Wilson said.

"Because the barriers are different, the messaging has to be different from any other HIV communications," said Wilson. "We have to understand their stories and what they're facing."

UCSF's Oakland and Sacramento-based strategy will focus on the ultra-personal, using one-on-one and group-based medical appointments during special clinic hours at La Clinica De La Raza in Oakland, and Gender Health Center in Sacramento.

The Sacramento clinic, for instance, has a long and proud reputation in the community for meeting transgender women's needs - offering, in addition to clinical care, name change clinics and low-cost emotional counseling. For PrEP, they will offer a "drop-in group," then pull women out for one-on-one medical appointments, Sevelius said.

"Trans women often avoid medical care due to stigma," she said. Through dedicated clinics, "we hope to build a sense of women's community support."

"We think what they really need is in-person personalized support - and community-level empowerment," Sevelius said. "Their issues run so deep."

The Southern California site will enroll 300 transgender women and men to test a transgender-focused "case management approach." To boost medication adherence, they are using a text messaging reminder system - with daily reporting of doses by text messaging.

People who miss doses will get a phone call, asking: "What's going on?" UC San Diego's Morris said. Of these, half will get what's called "motivational interviewing" - a clinical strategy designed to enhance a person's client motivation for change, through counseling.

"People lead complex lives - you need to get a feeling of what is causing them not to take their pills. It could be a certain life circumstance," he said. "Then you 'problem solve'...coming up with a plan, driven by the patient, to solve that problem."

"In everybody's mind," said Morris, "what we want to know is: Can they take it? Will it show the same efficacy as in other studies?"

Robyn Learned is buoyed by CHRP's new commitment to find, count, connect, and support transgender people - something she never experienced when starting her own journey 13 years ago. As society has changed, public health and medicine have, too.

As she works with transgender clients at Sacramento's Gender Health Study, she believes its mission - bundling PrEP with hormone therapy as part of a comprehensive package of personalized services, delivered in a place they feel secure - holds promise.

"There are really very little other ways of getting to these extremely marginalized populations," she said. "You need to make it really easy for them, as pain free as possible."

If successful, she said, "I think it will revolutionize everything."

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