

California HIV/AIDS Research Program

Program Director

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Mission

The California HIV/AIDS Research Program supports excellent, timely, and innovative research that is attentive to the needs of California and that accelerates progress towards prevention and a cure for HIV/AIDS.

Context: The HIV/AIDS Epidemic in California

The HIV/AIDS epidemic has taken a great toll on the people of California over the past 33 years. The number of persons living with HIV/AIDS continues to grow, with an estimated 133,000 Californians living with HIV/AIDS in 2012, an increase of 22% since 2008. The estimated annual cost to care for those living with the disease in California is approximately \$1.8 billion in state, federal and other resources. **In 2010, the California epidemic grew faster than that for any other state, and currently ranks second only to New York for the number of persons living with HIV/AIDS.** While many people with HIV/AIDS are living longer and healthier lives due to advances in care and treatment, about one in seven Californians with HIV are unaware of their status and only 55% of those infected are receiving care, placing them at greater risk for infecting others. In addition, the California epidemic disproportionately affects diverse and disenfranchised populations, particularly African Americans, who are being diagnosed at a rate more than five times that of whites.

CHRP Program Goals and Niche

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 has distributed and monitored more than \$250 million in state funds for HIV/AIDS research. The FY 2013-2014 CHRP budget is \$8,753,000. The program remains highly regarded by advocates and the legislature, as evidenced by its inclusion in the state budget every year at the request of the legislature. Current stakeholder and legislative support for CHRP stem from the Program's success in launching and funding key research initiatives which directly address the most important issues in California as identified by HIV/AIDS advocates and policy leaders. Recent highlights and key benefits to California include:

- **The largest and one of the first multi-site studies in the U.S. to test a new HIV prevention pill in high-risk uninfected populations. CHRP funding is matched by an industry gift of \$20 million in drug product**
- **The first effort nationally to assess the benefit of a key provision in the Federal Affordable Care Act (the patient-centered medical home) for people living with HIV**

- **Launching and funding the only collaborative HIV/AIDS Policy Research Centers in the U.S.**
- **More than eight dollars in federal and other grant support have been generated for every dollar invested by CHRP in California-based pilot research**
- **More than 25% of Californians living with HIV infection and in care are served by clinics funded by CHRP through its strategic research initiatives**

Based upon statewide input from surveys of key thought leaders and stakeholders in California, CHRP has identified four niche areas to focus its resources and efforts to benefit California:

1. **Strategic initiatives to curb the California HIV/AIDS epidemic:** California is at a crossroads in the HIV/AIDS epidemic. For the first time, we have the tools to potentially alter the course of the AIDS epidemic in California. Two new emerging strategies to drive down and potentially end the epidemic include interventions to provide an HIV prevention pill to uninfected persons, and interventions to identify and treat HIV-infected persons to reduce their transmission of virus to others. These two intervention approaches are estimated to reduce HIV transmission by more than 90%, thus leading to a potentially significant reduction in the epidemic in California. Given the significance of the epidemic in California, it is imperative for UC to take a leadership role in testing and evaluating these unique strategies in the state (see Initiative #1 below).
2. **Strategic initiatives to develop and evaluate new models of service delivery for HIV/AIDS care and prevention:** California and UC are taking a leadership role in health care reform in light of passage of the Federal Affordable Care Act. CHRP sponsored a multi-year statewide input and planning process to identify and evaluate potential strategies to improve care and treatment services for persons with HIV/AIDS in California. The recommended strategy that emerged was the development and utilization of the patient-centered medical home (PCMH) approach to care. This approach is expected to improve utilization and quality of care with a potential for reduced costs. Given the tremendous costs to California to care for persons with HIV/AIDS, it is critical to test and evaluate this new approach which has the potential to save scarce state resources. (See Initiative #2 below).
3. **Policy research initiatives:** Evidence-based policy recommendations are needed to help drive informed HIV/AIDS policy in California. UC is taking a leadership role by conducting evidence-based policy research to inform policymakers regarding the best approaches to reduce costs and improve care and prevention in California for persons with or at risk for HIV/AIDS (see Initiative #3 below).
4. **Leverage and training in basic biomedical, clinical, and social/behavioral sciences:** Basic biomedical science research is the pipeline for future innovations and

interventions in HIV/AIDS. Innovations in social/behavioral and clinical sciences can lead to new interventions and approaches to address the epidemic in California. UC needs to continue to take a leadership role in providing start-up (pilot) funds to support innovative research and training in these areas. Although the Federal government is also active now in sponsoring this type of research, the federal agencies tend to not support the most innovative, risky, or novel research. CHRP funds allow UC investigators and others to test innovative ideas and to leverage successful ideas with follow-up funds from other sources (see Initiatives #4 and #5).

Initiative 1: The Epidemic Interventions Demonstration Project

In 2012, three collaborative teams of investigators were awarded four-year grants totaling nearly \$18 million to test a potential HIV prevention pill among high-risk HIV-uninfected persons in several California communities. The studies also examine new strategies to engage and retain people living with HIV in care and treatment. Both of these strategies are expected to help curb the HIV epidemic in California.

The collaborative teams of investigators are offering the HIV prevention pill – part of an intervention known as PrEP (pre-exposure prophylaxis with antiretroviral drugs) – to high-risk uninfected men who have sex with men (MSM) and to transgender women (male to female transgendered persons) located in Los Angeles, San Diego, Long Beach, Oakland, Richmond, and Berkeley. These investigators are also assessing the implementation of TLC+ (testing and linkage to care plus treatment), a strategy to locate, engage, and retain HIV-infected persons in care and start them on life-saving treatment for their HIV infection. More than 4,000 Californians will participate in these three studies. Matching support valued at \$20 million (in the form of the drug product *Truvada*) is being provided by Gilead Sciences, Inc. of Foster City, CA.

This is the largest PrEP/TLC+ demonstration project in the U.S., and is the first to test PrEP in several communities in California. In these demonstration projects, PrEP is delivered as part of a comprehensive prevention package including risk reduction counseling and sexually transmitted infection screening. Importantly, these studies are designed to address the epidemic in the most difficult-to-reach patient populations in high risk communities, thus providing the greatest impact and benefit by providing research-based interventions to study participants.

Initiative 2: Patient-Centered Medical Home Demonstration Project

Five California health care provider organizations were awarded \$6.3 million over three years to establish Patient-Centered Medical Home (PCMH) Demonstration Projects in Alameda, Los Angeles, San Diego, and San Francisco counties. The initiative is evaluating the effectiveness of PCMH models of care for people living with HIV, which holds the promise of reducing costs, improving care coordination, and increasing quality and outcomes of care. A PCMH refers to an

integrated system or group of providers of care, treatment, prevention and support services that provides coordinated, high quality, client-centered services. A PCMH often utilizes electronic portals and record systems for improved coordination between providers and communication with patients. Examples of PCMH services which can be linked and coordinated include out-patient care, home health care, nutrition, mental health, and pharmacy. The PCMH model is now a key new component of the Federal Affordable Care Act.

This is the first PCMH research initiative in the U.S. focused on people living with HIV. This research will provide tremendous value to HIV care providers, policy makers, and health care system planners in California and nationwide. Moreover, nearly 12,000 Californians with HIV or about 16% of those receiving care in the state will benefit from improved services through this study. Finally, this demonstration project has significant implications in the design and delivery of care to persons with other chronic diseases such as diabetes and hypertension.

Initiative 3: Collaborative HIV/AIDS Policy Research Centers

In 2012, two Collaborative HIV/AIDS Policy Research Centers were awarded \$4.2 million over four years to support timely, objective, and rigorously conducted research and policy analysis that addresses critical issues related to HIV/AIDS care and prevention in California. The research centers are comprised of multi-disciplinary teams of investigators working in partnership with care providers, consumers, advocates, and policymakers. One policy research center is a collaboration between UCLA, AIDS Project Los Angeles and the LA Gay and Lesbian Center. The other center is a collaboration between UCSF, the San Francisco AIDS Foundation and Project Inform. **These are the only collaborative HIV/AIDS Policy Research Centers funded in the U.S., with California once again leading the nation in policy and evaluation research.**

The work of the Policy Research Centers is divided into two components. The first is “rapid response”, which entails short-term research projects designed to quickly address questions that emerge in a dynamic health policy environment. Projects have included modeling potential state AIDS Drug Assistance Program (ADAP) savings by supporting HIV patient enrollment in federally-supported Pre-Existing Conditions Insurance Pools (PCIPs); and conducting a cost-benefit analysis of enhanced surveillance efforts on federal funding for California. The second component includes longer-term research projects including examining the impact of the Federal Affordable Care Act on HIV services; analyzing Medi-Cal data to estimate the impact of proposals to limit physician visits, capping prescriptions, and charging co-pays; and examining various HIV workforce issues, such as the aging and specialty mix of physicians who provide HIV treatment in California.

Initiative 4: Investigator-Initiated Pilot Research Awards

CHRP provides start-up funds (pilot awards) for the development of cutting edge research by investigators in California, providing critical leverage in bringing subsequent federal and private

dollars to UC and the state. A **2006 survey of California investigators found that more than eight dollars in federal and other grant support was generated for every dollar invested by CHRP in California-based pilot research.** In addition, the survey found that about 1.5 publications were generated for each \$100,000 spent on pilot research. HIV/AIDS Pilot grants were awarded in the following scientific areas in the three fiscal years from FY 09-10 to FY 11-12:

Awards in Social and Behavioral Sciences

24 investigator-initiated and community-collaborative grants totaling \$4.9 million have been awarded for social and behavioral research focusing on men who have sex with men, women, transgender women of color, youth, and aging populations. Examples of funded proposals include:

- Structural Alcohol and HIV Risk Intervention in Gay Bar Patrons (UCSF)
- Adapting and Evaluating SISTA for Transgender Women of Color (UCSF)
- Determinants of Successful Aging Among Older HIV+ Persons (UCSD)

Awards in Basic Biomedical Sciences

32 grants totaling \$3.7 million have been awarded for investigator-initiated biomedical research and research training. Examples of funded proposals include:

- Targeted Delivery of Mucosal HIV Vaccines to Human M Cells (UCLA)
- Developing Inhibitors of SEVI-enhanced transmission of HIV (UCSD)
- Site-Specific Anti-HIV Gene Therapy (USC)

Awards in Clinical Sciences

Six grants totaling \$1.6 million have been awarded. Examples of funded proposals include:

- Aging and Non-AIDS Morbidity in HIV (Stanford)
- Self-Screening HPV and Anal Dysplasia in HIV Infected Women (Stanford)
- Vitamin D and Immune Activation in Chronic HIV Infection (UCLA)

Initiative 5: Investigator-Initiated Training Awards

CHRP provides funds to support dissertation and postdoctoral research fellowships under a designated mentor/advisor in a basic biomedical field related to HIV/AIDS. Twenty dissertation and 17 postdoctoral research fellowship grants totaling \$2.3 million have been awarded in the past three fiscal years. Examples of funded projects include:

- P-TEFb and Brd4 in HIV-1 Transcription and Latency (UCB)
- BST-2 downregulation and enhancement of HIV-1 release by vpu (UCSD)
- Role of microRNAs in the Pathogenesis of AIDS-NHL (UCLA)