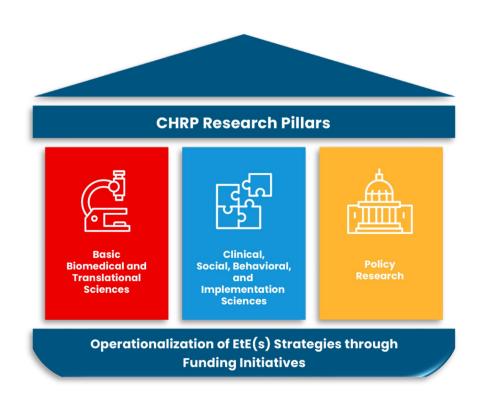


# Project Updates by Research Pillar and Portfolio September 2025



#### **Basic Biomedical and Translational Science**



## Portfolio: Basic Biomedical and Translational Science Discovery Initiative 2024 to 2026

PI: Mohamed Bouzidi – Vitalant

PI: Jennifer Dan – UCSD

PI: Jocelyn Kim – UCLA

PI: Sarah LaMere – UCSD

PI: Yusuke Matsui – The Gladstone Institutes

PI: Wenli Mu – UCLA

PI: Mattia Trunfio - UCSD

#### **Enhancing Anti-HIV Gene Therapy Through Epigenetic Modulation**

**Background:** CRISPR-Cas9 excision of the HIV genome is a promising strategy for an HIV cure. However, epigenetic features, including DNA methylation and chromatin condensation at the HIV integration site, may impede anti-HIV gene editing. In this study, we investigated the impact of an FDA-approved DNA methyltransferase inhibitor, 5-Aza-2'-deoxycytidine (5-Aza) and chromatin state on CRISPR-Cas9 editing efficiency.

**Methods**: HIV-latently infected J-Lat clone 11.1 was treated with DMSO (control) or 5-Aza (6.25nM), RG-108 (a 5-Aza analog, 10nM) and budesonide (a methylating agent, 10uM) for 72 hours and nucleofected with anti-HIV CRISPR-Cas9 ribonucleoproteins (RNPs) targeting the viral long-terminal repeat (LTR) promoter region. After 48 hours, DNA was extracted, and the LTR region was PCR-amplified, purified, and subject to Sanger sequencing. Sequences were analyzed using Tracking of Indels by DEcomposition (TIDE) to infer editing efficiency. Additionally, chromatin state of 6 J-Lat clones (5A8, 6.3, 9.2, 10.6, 11.1 and 15.4) was assessed using bulk ATAC-Sequencing. 3 clones were chosen based on their chromatin state at the integration site (open, closed and intermediate chromatin) and nucleofected with Cas9-RNPs targeting the HIV LTR. DNA was then isolated, LTR region PCR amplified, purified and subjected to Sanger Sequencing followed by TIDE analysis.

**Results:** J-Lat cells treated with 5-Aza and RG-108 showed a global methylation level 2-folds and 1.8 lower than control, where budesonide increased the global methylation levels by roughly 3 folds. Editing efficiency in 5-Aza treated cells was 3-fold lower compared to control. RG-108 and budesonide treated cells showed similar levels of gene editing. Epigenetic state on the other hand did not impact the editing efficiency.

Conclusions: Anti-HIV editing is impeded by demethylation of the HIV genome. As methylation of HIV provirus is on of the mechanism of provirus latency, our data suggest that the active HIV reservoir may be refractory to excision approaches. While hypermethylating drug budesonide did not seem to have an impact on J-Lat cell line, hypermethylation through other methods such as the CRISPRoff method should be further investigated in clinical setup in combination with anti-HIV gene editing approaches.

**Title:** Probing the HIV Viral Reservoir for HIV-specific killer cells

Team Members: Jennifer Dan, M.D., Ph.D. and Osirus Eisenman, B.S.

**Abstract**: One of the foremost barriers to HIV cure is the latent viral reservoir. Despite antiretroviral therapy (ART), HIV lies dormant within tissues and various immune cells. Once ART is stopped, HIV re-emerges from these tissues and immune cells. Tissues such as lymph nodes serve as a site for the HIV reservoir.

Lymph nodes contain a specific type of CD4+ T cells called a T follicular helper (Tfh) cells. The normal function of a Tfh cell is to provide help in the production of antibodies needed to neutralize pathogens. However, HIV can lie latent dormant within these Tfh cells.

A few years ago, we discovered "killer" Tfh cells in tonsils, which are secondary lymphoid organs. These cells express the cytotoxic enzyme granzyme B and are capable of killing cells. We developed an assay to identify antigen-specific T cells and have used this assay to identify HIV-specific CD4+ T cells.

Studying the HIV reservoir has been hampered by difficulty in obtaining viable tissue specimens. We utilized The Last Gift Study and will continue to obtain lymph nodes from persons with HIV. The Last Gift Study is a unique cohort of altruistic persons living with HIV with life shortening illnesses who participate in HIV cure-related research. Upon their death, a rapid autopsy is conducted within 6 hours of death. This Gift provides viable tissues for HIV reservoir research.

**Goal**: We will identify HIV-specific "killer" Tfh cells within lymph nodes and assess the quality of these cells.

**Progress**: Through the Last Gift Study, we have acquired lymph nodes from 4 persons with HIV and 1 person without HIV. Through the National Disease Research Institute, we have acquired additional lymph nodes from 18 persons without HIV. With our AIM assay, we have identified antigen-specific Tfh cells within lymph nodes. One obstacle we have faced is obtaining a large amount of viable cells to run additional studies.

Project Title: Targeted CAR-NK Therapy Extends Time to Rebound and Decreases HIV Reservoir Size Jocelyn Kim

This study evaluates an antigen directed natural killer cell therapy for HIV reservoir reduction during suppressive antiretroviral therapy. We engineered primary human NK cells with a CD4 D1D2 based chimeric antigen receptor that binds the conserved CD4 binding site on Env while lacking the determinants required for viral entry, thereby avoiding autoinfection of the effector cell. Transient mRNA transfection produced robust CAR expression. In co-culture with autologous primary CD4+ T cells infected with HIV NL4-3, CAR-NK cells selectively depleted p24 positive infected targets at low and high effector to target (E:T) ratios while sparing uninfected CD4+ T cells and showed no evidence of NK cell infection, confirming specificity and a favorable safety profile in vitro.

Efficacy was then tested in ART suppressed humanized mice infected with a CCR5 tropic barcoded HIV library. After four weeks of infection and six weeks of oral ART, mice received two intravenous doses of five million NK cells one week before and on the day of treatment interruption: D1D2 CAR-NK, GFP control NK, or no NK. D1D2 CAR-NK significantly delayed time to viral rebound relative to both control arms, whereas GFP NK did not differ from no NK, consistent with prior observations that unmodified NK cells during ART suppression are insufficient to affect rebound. Baseline human immune reconstitution and pre-ART plasma viremia were comparable across groups, supporting the interpretation that the CAR conferred the benefit. Once rebound occurred, plasma viral loads and cell associated RNA and total HIV DNA at necropsy were similar among groups, indicating that the barrier modified by CAR-NK cells lies before or at the moment of reactivation rather than during subsequent free virus spread.

Barcoded lineage tracking resolved how reservoir composition changed. Relative to controls, D1D2-CAR NK reduced the total number of rebounding viral barcodes within plasma and tissues and compressed clonal diversity. Thus rebound in treated animals arose from a smaller set of viral lineages. Despite this pruning, once any lineage reactivated it disseminated broadly, as viral RNA barcode sharing across organs was comparable between groups, indicating that post reactivation virion spread was not the major point of control.

To connect rebound viremia to its cellular origins, proviral barcode to integration site linkage with unique molecular identifiers was performed. D1D2-CAR-NK lowered the number and diversity of proviral barcodes that were detected in plasma during rebound and reduced inter organ sharing of those rebound competent clones, consistent with selective loss of migratory reservoir seeding cell clones. Integration site analyses further showed that average intra-organ infected cell clone sizes were similar across groups, while inter-organ sharing of integration sites fell significantly with D1D2 CAR-NK. Together, these data support a model in which CAR-NK cells primarily constrain the reservoir by eliminating infected cells poised to traffic and reseed multiple tissues, thereby reducing systemic complexity at rebound without altering local clonal expansion.

NK cell frequencies rose transiently after infusion and declined to near baseline within one to two weeks. Higher early post infusion NK levels trended with longer time to rebound, suggesting that improved persistence could enhance efficacy. Limitations include the humanized mouse model and the absence of latency reversal combinations, which may further augment clearance.

In conclusion, a CD4 D1D2 CAR confers to NK cells the ability to delay rebound after ART interruption and to compress the size and complexity of the rebound competent reservoir through selective pruning of migratory infected clones. These findings validate CAR engineered NK cells as a reservoir targeted immunotherapy and motivate strategies that extend persistence and combine with latency reversal to deepen and prolong reservoir depletion.

### 3D Chromatin Capture of HIV Proviral Expression Reveals Potential Epigenetic Regulators of HIV Latency

Megha S Srivatsa<sup>1</sup>, Nadejda-Beliakova-Bethell<sup>1,2</sup>, Sarah A LaMere<sup>1</sup>

<sup>1</sup>University of California San Diego, La Jolla, CA 92093, USA

<sup>2</sup>VA San Diego Healthcare System and Veterans Medical Research Foundation, San Diego, CA 92161, USA Author contact information: salamere@health.ucsd.edu; mesrivatsa@health.ucsd.edu

#### Introduction:

Following acute HIV infection, the viral DNA integrates into the genome and becomes latent. However, while the epigenetic mechanisms for silencing the inserted DNA likely present druggable targets for a cure, they remain poorly understood.

#### Context/Background:

The integrated HIV provirus interacts with host chromatin at distant sites. We hypothesized that a 3D examination of these sites in CD4+ T cells would overlap with known binding sites for chromatin modulators in the human genome to reveal currently unknown potential latency-driving epigenetic targets.

#### Methods:

Single cell (sc) Hi-C chromatin capture on a primary CD4+ T cell latency line was used to identify topologically associated domains (TADs) interacting with the provirus. These TADs were overlaid with known binding sites for transcription factors across the human genome using the ReMap database, identifying putative targets modulating proviral expression. STRING analyses was performed to reveal further associated chromatin modulators. Functional pathways for these transcription factors were examined using Reactome analysis. One select target was subjected to scCUT&Tag in a JLAT latency cell line to validate proviral binding alongside the repressive histone modification, H3K27me3.

#### Results/Outcomes:

Hi-C analysis returned 236 TADs interacting with the HIV provirus. The ReMap overlay revealed 785 unique potential transcription factors with binding sites in these TADs. Reactome pathway analysis of the ReMap list showed significant enrichment of epigenetic regulation and chromatin remodeling pathways, including those regulating endogenous retroelements. One chromatin modifier, DPF2, was subjected to Single cell Cleavage Under Targets and Tagmentation (CUT&Tag) in JLAT cells (an immortalized CD4+ T cell HIV latency line). Results of CUT&Tag showed significant binding of DPF2 to the provirus, especially in the *vpu/env* region. The binding profile of DPF2 exhibited overlap with enrichment of repressive histone modification H3K27me3, as well as the original DPF2 TADs sequenced in the primary CD4+ T cell latency line. STRING analysis of DPF2 returned several more factors overlapping with the Hi-C data, including ARID1A, ARID1B, BRD7, and SMARCC1.

#### Conclusions and Future Directions:

Single cell Hi-C chromatin capture of a primary CD4+ HIV latency model has revealed many putative epigenetic and chromatin modifying factors associated with HIV latency, both known and unknown. Validation of proviral binding by BAF complex member DPF2 using scCUT&Tag and corroboration using protein interaction analyses has further identified novel putative chromatin modifying enzymes that regulate latent HIV reservoirs. Single cell Hi-C and scCUT&Tag are currently being used in the same fashion in CD4+ T cells isolated from clinical tissue samples of people with HIV to identify and validate *in vivo* targets, including DPF2.

#### One-Page Study Summary

PI Name: Yusuke Matsui, Institutes: Gladstone Institutes

Project Title: Mapping the HIV Reservoir in Microglia Subsets

Microglia are one of the crucial tissue-resident target cells for HIV-1, but which microglia subsets are most significant in HIV-1 infection is not fully understood. Even in antiretroviral therapy (ART), clones of HIV-1 directed to myeloid cells have been intermittently detected intracranially, independent of the body circulation, suggesting that microglia form a latent reservoir.

Our hypothesis is that subset characteristics of microglia influence susceptibility to HIV and the establishment and maintenance of latent infection. Because microglial subsets differ across brain regions, we generated three types of brain organoids from iPSCs (WTC11): cerebral organoids, choroid plexus organoids, and dorsal—ventral forebrain organoids. At day 50, organoids were assembled with iPSC-derived microglia from the same line (WTC11) and maintained for 10 days to establish microglia-containing organoids. To distinguish actively from latently infected microglia, we employed dual-reporter HIV-1 DuoFluo (active mKusabira-Orange2-positive, GFP-positive], latent [mKO2-positive, GFP-negative]); however, expression of mKO2 under the EF1α promoter was weak in primary microglia, limiting the ability to isolate infected cells. We successfully quantified actively and latently infected cells using new dual-reporter virus in which the EF1α promoter was replaced by the Pgk promoter (active [mScarlet3-positive, HSA-positive], latent [mScarlet3-positive, HSA-negative]). In cerebral organoids, microglia were sevenfold more likely to establish latency at day 6 post-infection compared to microglia in 2D culture. The efficiency of microglial incorporation into organoids has improved markedly since the start of the project, and single-cell analysis is planned as the next step.

In addition, we have implemented MEA (multielectrode assay) technology to enable real-time analysis of organoid function and are currently investigating how viral production relates to neural activity in HIV-infected organoids.



#### CHRP Grantee Meeting – September 15 - 16, 2025 Poster Session – Template for Poster Abstracts

#### **Funded Project Information**

PI Name: Wenli Mu

Lead Institution(s) or Community Based Organization(s): University of California, Los Angeles Project Title: Enhancing Anti-HIV Immunity through Multilineage CAR Cells Derived from

Hematopoietic Stem Cells

#### **Abstract Information**

Title: Enhancing Anti-HIV Immunity through Multilineage CAR Cells Derived from Hematopoietic Stem Cells

Author Names (lead author is first): Erik Gramajo, Jedric Gonzales, Margret Wang, Valerie Rezek, Heather Martin, Scott Kitchen, Wenli Mu

Author Affiliations/Institutions: Division of Hematology/Oncology, Department of Medicine, University of California, Los Angeles.

#### **Abstract Text (limit 300 words)**

Despite the success of antiretroviral therapy (ART) in controlling HIV replication, ART fails to clear the infection, and viral rebound occurs upon therapy cessation from latent reservoirs. Chimeric Antigen Receptor (CAR) Therapy offers a promising approach by engineering immune cells to enhance their response to HIV and eliminate infected cells. Specifically, CD4-CAR-modified HSPCs, which can differentiate into multiple hematopoietic lineages including T cells, macrophages, and NK cells in humanized mice and nonhuman primates (NHPs), show potential for broader and stronger immune responses against HIV. We aim to optimize the function of anti-HIV CAR multilineage CAR immune cells by selecting candidate intracellular domains that enhance different immune cells. By developing various CAR constructs, incorporating D1D2-CAR with macrophage intracellular domains (FcRγ and PILR-beta), as well as the NK intracellular signaling (DAP12), we aim to enhance multilineage CAR immune cell efficacy. Additionally, we incorporated CD40 and OX40, which have shown to mediate NK cytotoxicity when paired with CD40L, and engage a prolonged CAR-T response when paired with DAP12.

Our in vitro data show that DAP12 enhances CAR-NK cytokine secretion. The FcR $\gamma$  and PILR-beta incorporated into CAR-MQ showed comparable phagocytosis to the original D1D2-41BB-CD3 $\zeta$  CAR molecule. Notably, combining FcR $\gamma$  with OX40 and PILR-beta with DAP12 intracellular signaling significantly improves CAR T proliferation and cytokine secretion. These two CAR constructs also enhanced CAR-T memory differentiation in long-term co-cultures with target cells. We have selected three promising CAR constructs to move forward into in vivo studies. These constructs will be evaluated for their anti-HIV effects in chronic HIV-infected humanized mice, with the goal of boosting both multilineage CAR immune cells and endogenous cytotoxic T lymphocyte function while targeting various anatomical reservoirs.

#### Spinal cord as a distinct site of HIV persistence and dispersal

**Investigators:** Mattia Trunfio, Sara Gianella, Cheryl Dullano, Stephanie Solso, Gemma Caballero, Pinyi Du, Brady Lapke, Caroline Ignacio, Magali Porrachia, Patricia Riggs, Davey Smith, Antoine Chaillon

**Background:** HIV persistence in the central nervous system (CNS) remains a major barrier to eradication. While the brain has been extensively studied, the spinal cord (SC) has received little attention despite its central role in neuroimmune signaling and connectivity. Whether the SC represents a distinct HIV reservoir, contributes to viral persistence, or facilitates dispersal across the CNS is largely unknown.

#### **Objectives**

- 1. **Characterize HIV reservoir size** in five SC segments (pons, medulla, cervical, thoracic, lumbosacral) relative to other CNS, blood, and peripheral tissues available in the Last Gift cohort;
- 2. **Determine viral activity (HIV transcription) and diversity** in SC compared to brain regions and periphery;
- 3. **Define the role of the SC in viral migration and dispersal** within the CNS and between CNS and periphery;
- 4. Assess how antiretroviral (ARV) penetration and inflammation shape SC reservoirs.

**Methods:** Postmortem tissues were collected within 6 hours of death from Last Gift participants. HIV DNA and cell-associated RNA (msTat/Rev) were quantified by ddPCR. Viral diversity and compartmentalization were assessed by full-length single genome sequencing of *env*. Bayesian phylodynamic models were used to evaluate viral migration. Ongoing analyses include ARV tissue concentration (via mass spectrometry) and CSF biomarker profiling. Mixed-effects models were applied to compare HIV measures across tissues.

#### **Key Findings to Date**

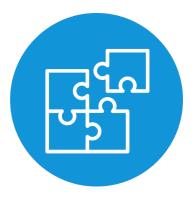
- Reservoir size and activity: HIV DNA and RNA levels in SC segments were lower than in PBMCs and
  overall similar to other CNS regions (thoracic SC showed higher HIV DNA than occipital cortex);
- Transcriptional activity: Basal ganglia exhibited higher HIV RNA than SC or other CNS tissues;
- **Viral diversity:** SC displayed higher *env* diversity compared to frontal cortex and hippocampus; overall SC diversity resembled blood (significantly higher than other CNS areas);
- **Migration dynamics:** Phylodynamic models consistently revealed HIV dispersal between SC and other CNS regions, and the SC was the primary recipient and donor site of these movements;
- **Compartmentalization:** Brain regions showed greater evidence of compartmentalization than SC, suggesting the SC is less isolated and more interconnected with blood;

**Significance:** This project provides the first comprehensive analysis of HIV reservoirs in the human spinal cord, revealing it as both a diverse sanctuary and a hub for viral migration. Findings highlight the SC's central role in sustaining CNS and systemic reservoirs, filling a critical knowledge gap and informing next-generation HIV cure strategies.

**Reference:** for preliminary data see Abstract #168, Conference on Retroviruses and Opportunistic Infections, CROI, March 9-12, 2025, San Francisco, CA, US.

Corresponding author: mtrunfio@health.ucsd.edu

#### Clinical, Social, Behavioral, and Implementation Sciences



Portfolio: Implementation Science
2021 to 2025

PI: Erik Storholm – SDSU

PI: Janet Myers – UCSF

## **PrEP Well**



A PrEP program by the community, for the community

PrEP Well is a program housed at the Trans Wellness Center (TWC)in Los Angeles that helps clients navigate to pre-exposure prophylaxis (PrEP), a medication to prevent HIV infection (CHRP H21IS3484). The program is led by bilingual members of the TGNB community and staff. Participants who meet eligibility criteria are enrolled in the program, prescribed PrEP, assisted with prescription insurance coverage, and can often pick up PrEP the same day. During this 90-day program, clients have three program visits, and can earn up to \$225 plus additional prizes that celebrate and support trans and non-binary communities.

## PrEP Well is proudly:

Trans-Led
Patient-Centered
Community-Based
Gender-Affirming
Fun, Easy, and Convenient

#### The PrEP Well team:



Erik D. Storholm (PI), Kimberly Ling Murtaugh, Alex Dopp, Carrie Nacht, Risa Flynn, Chloe Opalo, Mika Baumgardner



PrEP Well was initially developed as a 3-year Implementation Science Award (CHRP H21IS3484) to assess the fit of PrEP services at the TWC. After PrEP Well began, clients and staff felt the need for additional support to implement PrEP Well.

Thus, our team secured additional funding to add a behavioral economic incentives component, wherein clients earned extra prizes for positive decisions in addition to research incentives (P30MH058107-26S5). Clients can earn up to 3 spins on a prize wheel per visit for a chance-based incentive of different values. The prizes were selected based off of community input and often were created by trans-owned businesses.

#### Specific aims:

- 1. Assess the fit of PrEP Well at the TWC
- 2. Implement PrEP Well at the TWC
- 3. Sustain PrEP Well at the TWC.
- 4. Assess the acceptability, appropriateness, feasibility, and preliminary effects of behavioral economic incentives to support *PrEP Well* implementation.



## **PrEP Well**





#### **Exploration**

- Identify TWC clients' health needs and service preferences
- Prioritize service gaps to address
- Select intervention (PrEP) that fits and is feasible for setting

#### **Preparation**

- Assess fit of PW with TWC's goals and client needs
- Identify barriers and facilitators to PW implementation
- Understand services

   (e.g. hormone therapy
   that PrEP will link with)

#### **Implementation**

- Secure leadership commitment
- Define roles and responsibilities
- Plan coordination, training, and evaluation
- Align with financial and community resources

#### **Sustainment**

- Make PrEP services routine
- Integrate intervention evaluation into current service evaluations
- Identify options for long-term financial and technical support



## What PrEP Well clients are saying:

"I love that the whole thing was trans-oriented, so it was very personable to my community. The colors, the theme, the prizes very thoughtfully picked out." "I have peace of mind because I use PrEP... you don't trade that for anything."



"The TWC gives participants a place where they feel comfortable to come. It's not some new outreach program...it helps so much more so that you know your health, and you can stay sexually protected."

#### The PrEP Well impact:

170+ participants enrolled

8 trans-owned business partners

72% of program completers were consistently adherent to PrEP

100% Trans Wellness Center staff and provider approval



Email: TWCprepstudy@gmail.com | Phone: (714) 900-2878





#### Consumer Preferences for the Delivery of Prevention Services among Individuals Leaving Jail

Team Members: Janet Myers (PI), Asa Clemenzi-Allen (Co-PI), Emily Dauria (Co-I), Starley Shade (Co-I), Illana Garcia-Grossman (Fellow), Graham Hinchcliffe (Project Director), Sue Napierala and Erica Brown (DCE Consultants)

Background: Changes in the availability of treatments (long-acting injectables and new therapies) and shifts in service delivery modalities due to the COVID-19 pandemic have created opportunities for matching evidence-based treatments to consumer preferences. This project assessed and leveraged consumer preferences in the design of a navigation intervention to promote linkage to HIV prevention and substance use disorder (SUD) treatment for people leaving jail in San Francisco.

Study Aims: Aim 1: To facilitate a three-year Community of Practice (COP) comprised of providers, CJI consumers and public health officials to foster the co-design of the study and the pilot program resulting from it.

Aim 2: To assess the current state of HIV prevention (perceived risk and need for PrEP) and substance use disorder (SUD) treatment needs and preferences for care among individuals leaving jail in San Francisco by:

Aim 2a: Conducting a discrete choice experiment (DCE) with individuals leaving jail to assess their preferences for HIV prevention and substance use disorder treatment implementation strategies.

Aim 2b: Evaluating gaps in PrEP initiation in jail and immediately following release for people at risk for HIV acquisition using San Francisco County Jail's electronic medical records and existing administrative datasets in order to quantify missed opportunities for HIV prevention.

Aim 3: In collaboration with the COP, to package the strategies into a program that is responsive to the consumer choices resulting from the DCE and conduct an implementation pilot study of the program among individuals who are linked to it leaving jail.

#### Results from the Discrete Choice Experiment (N=152):

- Among individuals surveyed in the DCE, Clinic type and medication administration were the most important attributes in the survey.
- Strongest preferences were for service delivery in a setting that serves the general population over specialized settings for people with incarceration experience (62%, OR 3.02) and for medication to be given via a monthly shot, over a daily pill (57%, OR 2.03).
- Preferences regarding when services were initiated (e.g., before leaving jail, at the time of release, or following release) and appointment visit/type after release (e.g., appointments, drop-in visits, mobile care delivery) showed no statistical significance.

#### Results from the Gap Analysis using jail health record data:

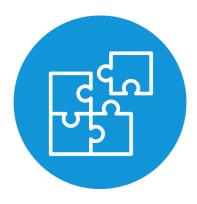
- We assessed PrEP eligibility among those in custody for over a week (1/1/2019 9/30/2021) and whether decarceration during the COVID-19 pandemic impacted PrEP eligibility.
- Approximately one in six jail encounters lasting at least seven days were eligible for PrEP.
- Few eligible individuals in SFCJ are already on PrEP, demonstrating missed opportunities for PrEP initiation during episodes of incarceration, particularly among people who spend at least 7 days in jail.
- Although the total number of PrEP-eligible encounters decreased after the start of the pandemic, the proportion of PrEP-eligible encounters remained stable, indicating that risk is an enduring phenomenon.

#### **Results from the Expert Interviews:**

- Experts from settings of incarceration outside of California unanimously endorsed the integration HIV and SUD services. Suggested models/recommendations:
- Co-located and integrated wrap-around service hubs near jails, incorporating Hep-C and pharmacy.
- Increased and expanded peer navigation and release planning.
- Integrate gender-affirming, culturally competent and trauma-informed care.

Conclusion: The jPREFS project provided a unique opportunity for translating research into practice. Using multiple methods and stakeholder input, we generated a roadmap for integrating HIV prevention and SUD treatment within one carceral and community reentry setting – and have piloted implementation of the model at the C-CARES clinic at San Francisco General Hospital. Results offer a scalable framework that can inform future efforts of this kind.

#### Clinical, Social, Behavioral, and Implementation Sciences



#### Portfolio: Community-Centered Research Collaboratives to Address Local HIV-Related Syndemics Across California

#### 2023 to 2027

Co-PIs: Ayako Miyashita Ochoa (UCLA), Bamby Salcedo (TransLatin@), and Sophia Zamudio-Haas (UCSF)

Co-Pls: Laramie Smith (UCSD), Malek Guerbaoui (San Diego LGBT Community Center)

Co-Pls: Carina Marquez (UCSF), Efrain Barrera (Mission Language Vocational School)

Co-Pls: Lois Takahashi (SJSU), Jury Candelario (APAIT Special Services for Groups)

### SW LEARN:

# Sex Work Lived Experience Affirming Research Network

Centered Community: Black, Latinx, Indigenous Trans Women of Color with Past or Current Experience with In-Person Sex Work in Los Angeles County







#### **Partners and Team Members:**

- Unique Woman's Coalition (UWC): Queen Chela Demuir
- TransLatin@ Coalition (TLC): Bamby Salcedo, Johanna Wallace, Suanne Mendez
- Sex Workers Outreach Project Los Angeles (SWOPLA): Ashley Madness, Tiff Lee, Luna de la Morte
- UCSF: Sophia Zamudio-Haas, Patric Prado, Luz Venegas, Jed Rodriguez
- UCLA: Ayako Miyashita Ochoa, Vanessa Warri, Kimberly Fuentes



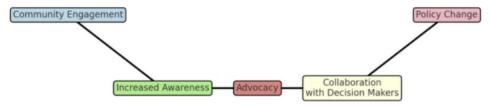
Research Question: Can a community-academic partnership expand to: create a research agenda centering community needs; select/adapt/implement an evidence-based intervention to improve health outcomes among BIPOC trans women who have experience in sex work; evaluate the impact of the intervention on health outcomes among study participants as well as the implementation of the intervention; and disseminate their results?

Intervention: Sheroes/Poderosas, a peer-driven health intervention for Black and Latinx transwomen engaged in sex work. Four-month duration, including six group meetings (2hrs each, over three weeks), three surveys. Meetings consist of games, discussion, health education, and mindfulness. Meeting themes include pride, empowerment, health & wellness, communication, self-defense, and self-care advocacy.

**Key Outcomes**: Research agenda; self-reported HIV and STI-related outcomes (testing; treatment); engagement in care index; social support; implementation outcomes.



- Aims: 1. Strengthen SW LEARN, establish a research agenda, and adapt an evidence-based intervention for sex workers by sex workers:
  - Implement the adapted HIV/STI program for Black, Indigenous, or other sex workers of color who
    are transgender ("trans") women; enroll 115 intervention participants and 15 SW LEARN
    implementation staff participants; study HIV/STI outcomes for intervention participants; conduct
    process evaluation of the coalition process for SW LEARN implementation staff; and
  - 3. Share findings with trans community members and policymakers to inform programs and policies impacting priority communities.



#### **Progress:**

- Strengthened SW LEARN via retreats and robust meeting schedule (30+ last year);
- Developed a trans women of color-centered research agenda and selected intervention;
- Adapted the intervention using bilingual workshops to test and refine sessions;
- New intervention session on community engagement and activism developed;
- Study protocol and intervention manual (for group facilitators) completed;
- Instruments all finalized;
- IRB approval and NIH Certificate of Confidentiality secured;
- Study website, REDCap system, and Calendy site finalized;
- Presented a workshop (National Transgender Health Summit) and poster (CHIPTS);
- Began manuscript of intervention adaptation;
- Student supplement yielded "transformative" mentoring in community-engaged research

**Next Year**: Collaborative expansion; launch enrollment; ongoing dissemination including social media. **Challenges**: Finalizing the facilitation manual; delays; how to address immigration status (or not); standardized scales that come from a deficit approach; how to minimize potential harm and avoid extractive research practices.



## THP: Trans Health Project

Centered Community: Black and Latina Transgender Women in San Diego

Partners: Black San Diego Pride, Proyecto Trans Latina, Transgender Health and Wellness Center, The T-Spot, The San Diego LGBT Center, San Ysidro Health, Urban Restoration Counseling Center, UCSD

















Team: Laramie Smith (Co-PI), Malek Guerbaoui (Co-PI), Marisol Leos (Co-PI), Courtney Johnson, Martin Ibarra, Diego Flores, Brany Barragan, Bliss Vasquez, Jocelyn Kennedy, Diva Ceasar, Jamie Woods, Jamie Arangure

Research Question: Using data from a new cohort of 115 community members, can we co-develop a new program to address syndemic drivers of HIV inequities among trans women, deliver that new program, assess it's impact, and identify what is needed to make the program work better and maintain it over time?



**Intervention:** Ambassador program, drop-in space, case management, trainings/workshops, urgency funds.

Key Outcomes: Sustained engagement in a statusneutral HIV care continuum, measured as HIV testing or viral load monitoring every 6 months over 18 months;

#### Aims:

- 1. Convene the Trans(C)ending HIV Syndemics

  Collaborative, comprised of representatives from

  Black and Latinx Trans-led Advocacy groups and

  from HIV and gender-affirming care providers in San Diego.
- 2. Integrate and implement an evidence-based intervention to co-address HIV and sex work / violence / substance use (SVS) related needs.

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lives in San Diego County?

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systemic barriers and

health outcomes AND get paid for it? **really.** 

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being a DOLL!

- 3. Evaluate impact on sustained engagement in a status-neutral HIV care continuum and other HIV and syndemic outcomes among 125 Black and Latina transgender women in San Diego.
- 4. Routinely disseminate the Collaborative planning process, progress, and results to our centered community, local stakeholders, and the scientific community.

#### Successes:

- Cooperation among partners, restructuring to elevate community members into leadership;
- All surveys/data collection tools programmed;
- Community cohort enrollment launched and dissemination events ongoing;
- Cultivation of research skills in the centered community;
- Collaborative meetings using study data for program decisionmaking process;
- Increased reach, rapport, and enrollment of Black trans women.



Next Year: Launch new program in January 2026!

**Challenges:** New leadership plan/funding structure; delays in funding required shifts in staff effort; staffing changes; uneven enrollment of two centered communities; effects of syndemic exposures on people required heightened flexibility and creative problem-solving.



## **UNIDOS EN SALUD:**

MULTI-DISEASE HIV TESTING HUBS FOR LATINE IMMIGRANT COMMUNITIES IN SAN FRANCISCO













**Partners**: Latino Task Force, Mission Language Vocational School, UCSF, San Francisco DPH

**Team**: Carina Marquez (Co-PI), Efrain Barrera (Co-PI), Rachel Abbott, Lisa Geronimo, Shalom Bandi, Noel Leon, Fernanda Amaya, Francisco Herrera, Sonia Alvarenga, Antonio Aguilar-Karayianni, Moctezuma Garcia.

#### Research Questions:

- 1. Can we leverage an established community-academic-city collaborative to *tailor and evaluate a* comprehensive, multi-disease testing program developed for and by the Latine immigrant community in San Francisco?
- 2. Can a co-designed community-based *peer-network home HIV and STI testing program* improve linkage to (a) HIV and STI testing and (b) prevention and care for Latine immigrant and day laborer communities?



Interventions: (1) Low-barrier multi-disease testing hub with community health approach: HIV and COVID testing, screening for diabetes and hypertension, linkage to syndemic-responsive services (financial, housing, mental health); (2) Home-based HIV/STI testing kits distributed by peers and community ambassadors.

**Key Outcomes**: Reach of HIV testing intervention; HIV testing yield; PrEP linkage; health education reach. **Aims**:

- 1. Identify multi-level barriers and facilitators to implementation of community health hub model of multi
  - disease testing among Latine immigrants in the southeast sector of San Francisco;
- Implement and evaluate a tailored community health hub model with statusneutral linkage to care;
- Optimize reach of HIV testing intervention via a social network strategy, including HIV self-tests.



#### **Successes:**

- Launched community-based HIV testing and community health hub with monthly "Convivio", "Comida y Salud" events to increase community awareness about HIV testing and prevention.
- Co-designed testing models with formative research and new collaborations:
  - Expanded collaborations with Day Laborers Collective (Nuevo Sol)
  - HIV testing survey; qualitative IDIs and CBO focus groups.
  - Partnered with SFDPH to identify facilitators and missed opportunities of HIV testing and prevention among Latine persons newly diagnosed with HIV in San Francsico from 2021-2023.
     Shared findings with SFDPH and Getting to Zero Collaboration.
  - Completed qualitative analyses on how to increase HIV testing among Latine immigrant communities and to guide development of our social network testing (Aim 3) and to refine our community health hub model (Aim 2).
  - Presented findings to San Francisco Getting to Zero Collaborative Fall Symposium, focused on Advancing HIV testing and prevention in the Latine community; presented qualitative findings at the International AIDS Conference 2025 in Kigali, Rwanda.
- Co-designed an implementation science study on network-informed strategies to distribute home HIV/STI testing kits with linkage to care. <u>Planning to launch Aim 3 in September 2025</u>.

**Next Year:** Formal study of implementation and effectiveness of social-network based home HIV/STI testing; iterative evaluation of social network-based intervention and multi-disease testing models; qualitative analysis for publications

**Challenges:** New immigration policies and landscape that increase barriers to accessing health-related services for the Latine immigrant community, changes in funding climate for CBO, ongoing stigma surrounding HIV testing and care.

#### <u>Unidos en Salud HIV Research Agenda</u>:

In the Latine community, we aim to:

- Increase HIV/STI testing uptake to ensure early diagnosis, link rapidly to status-neutral care and other services (e.g., food, job training, insurance).
- 2. Increase PrEP awareness and linkage
- Optimize community-led and implemented strategies to reach immigrant and marginalized Latine immigrant communities, with a specific focus on home-based HIV/STI testing.





# TRANSGENDER HEALTH/HOUSING/HIV EQUITY (T.H3.E.) PROJECT

FUNDED BY THE CALIFORNIA HIV/AIDS RESEARCH PROGRAM (H23PC5093)

#### RESEARCH QUESTION

Does HIV status neutral transitional/interim bridge housing (TIBH) for 6-12 months improve HIV outcomes for TGI Women\* experiencing unstable housing in Los Angeles and Orange Counties?

**KEY OUTCOMES:** Intervention: Transitional/Interim Bridge Housing (TIBH)

HIV Outcomes: HIV-: PrEP uptake/continuation

HIV+: durable viral load suppression; provider visits

RE-AIM: Reach, Effectiveness, Acceptability, Implementation

#### **RESEARCH TEAM**

#### **Principal Investigators:**

Lois Takahashi<sup>1</sup> (PI)
Jury Candelario<sup>2</sup> (Community PI)

#### **Co-Investigators**

Jazzmun Crayton<sup>2</sup>, Bamby Salcedo<sup>3</sup>, Karina Samala<sup>4</sup>, Karin Tobin<sup>5</sup>, Melissa Davey Rothwell<sup>5</sup>

#### **Research Team**

Abigail Winiker<sup>5</sup>, Morgan Clark<sup>2</sup>, a.b. Monzón<sup>2</sup>, Paolo Gutierrez<sup>2</sup>, Rene Snow<sup>2</sup>, Marc-Emil Sevilla<sup>1</sup>, Abril Baez Anguino<sup>1</sup>

#### **Partners**

Amanda Wahnich<sup>6</sup>, Jeffrey Vu<sup>7</sup>, Paulina Zamudio<sup>6</sup>, Rebecca Mares<sup>7</sup>

#### **Community Advisory Board**

Chantay Mackey<sup>8</sup>, Delilah Tanah<sup>9</sup>, Kadence King<sup>10</sup>, Lexi Matthews<sup>11</sup>, Lola Murray<sup>12</sup>, Michelle Darmary<sup>13</sup>, Veronica Fernandez<sup>14</sup>, Vivian Gallardo<sup>15</sup>

(1) San Jose State University, (2) Access to Prevention Advocacy Intervention and Treatment, a division of Special Service for Groups, Inc., (3) TransLatin@ Coalition, (4) Imperial Court of Los Angeles and Hollywood, (5) Johns Hopkins University, (6) Los Angeles County Department of Public Health, (7) Orange County Healthcare Agency, (8) Los Angeles Centers for Alcohol & Drug Abuse, (9) No Matter What, (10) SSG-BACUP, (11) Safe Space for Youth, (12)Trans Wellness Center, (13) Alianza TransLatinx, (14) St. John's Community Health, (15) Bienestar

#### AIMS:

- 1.TIBH Effectiveness: quasi-experimental design (n=200 TGI women); three data points: entry into TIBH (baseline); exit/discharge from TIBH; 6 month follow-up
- 2.TIBH Acceptability: qualitative interviews of 10-15 providers and 25-30 TIBH TGI women participants
- 3. Implementation: Annual survey of CAB members to assess inclusiveness and relevance
- 4. Reach: formative study using qualitative interviews of 25-30 TGI women participants (from Aim 2) to assess change in social networks from unhoused to transitionally housed

#### \*A NOTE ON TERMINOLOGY:

For the purposes of this study, we use the term Transgender, Gender nonconforming, and Intersex (TGI) Women to refer to individuals who were assigned male at birth (AMAB) and who align with a femme gender identity. According to a UCLA Williams Institute report,\*\* "TGI" has been adopted by community leaders as a collective term for gender-expansive identities. We recognize that not all participants may personally identify with the "TGI" term. We define "women" in its most inclusive sense, encompassing transfeminine, femme, and other identities within the TGI spectrum.

\*\* https://williamsinstitute.law.ucla.edu/publications/qol-tgi-los-angeles/



Christina Munguia, Clinical Therapist at Casa de Zulma (the first publicly funded housing program specifically for TGI women)

#### **RESULTS (AIM 1):**

• Recruitment: 224 referrals, 146 screenings, and 107 eligible participants (73% eligible of total screened)

#### Participant Characteristics:

- Language: 75% English and 25% Spanish
- Race/ethnic groups: 52% Hispanic/Latina, 18% Black, 16% White, 5% Indian/Native American, 3% Asian, 1% Native Hawaiian, 1% Middle Eastern
- Mean Age: 34.4 years (SD=11.1), IQR= 27-40
- Housing location: 92% in LA, 1% in OC
- Use of TIBH: 51% in TIBH for the first time
- Employment: 78% unemployed, 90% motivated to work

#### **Service Use:**

- 80% saw a primary provider in the past 90 days
- o 61% saw a dentist
- 55% report using mental health counseling
- 55% report using gender-affirming care
- 52% had their vision checked in the past year
- 42% used housing placement services
- 39% used recovery groups and 36% used addiction counseling
- o 39% used identification services, 32% used benefits case management
- HIV Status and Viral Load: HIV status: 26% HIV positive, 67% HIV negative 18% not sure of status; 25% of HIV positive reported a viral load check in the past 90 days
- PrEP cascade: Among HIV-negative participants, 96% were aware of PrEP, but only 35% were currently taking PrEP

#### YEAR 4 NEXT STEPS

- Complete data collection and analysis (Aims 1, 2, 4)
- CAB to co-design dissemination plan (Aim 3)



The Serenity House is the first and only Medi-Cal funded Residential treatment program dedicated to the transgender, intersex and non-binary populations.

APAIT está reclutando participantes para un estudio explorando los impactos de servicios de vivienda en la vitalidad de personas transgenero y los resultados relacionados con el VIH.

#### Elegibilidad:

- Inscrita/e o en proceso de inscripción en un programa de vivienda transicional
- Expresion femenina
- Identificarse como muxe/dos espiritus, transgénero, o no binarie





TINYURL.COM/TH3ESTUDY

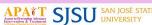


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**EARN UP TO** 

\$325 FOR PARTICIPATING!







JOHNS HOPKINS





Top to Bottom: Study recruitment flyer in Spanish; Collage hanging in Casa de Zulma; The research team and the CHRP team during a recent site visit.





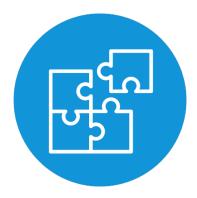








#### Clinical, Social, Behavioral, and Implementation Sciences



Portfolio: Community-Centered Demonstration Projects to Support Implementation of Long-Acting Injectable PrEP Adoption Across California

2024 to 2028

PI: Betty Dong – UCSF

PI: Risa Hoffman – UCLA

PI: Kimberly Koester – UCSF

PI: Sheldon Morris - UCSD

PI: Robert Deiss – UCSD

### Harnessing the Potential of Pharmacy Provision of Long-Acting Pre-Exposure Prophylaxis (PrEP)



Betty J. Dong, PharmD Principal Investigator UC San Francisco

San Francisco



Ayako Miyashita Ochoa, JD Co-Investigator UC Los Angeles



Raiza Beltran, PhD Co-Investigator University of Minnesota



Emma Gunderson, EdD Project Manager UC San Francisco







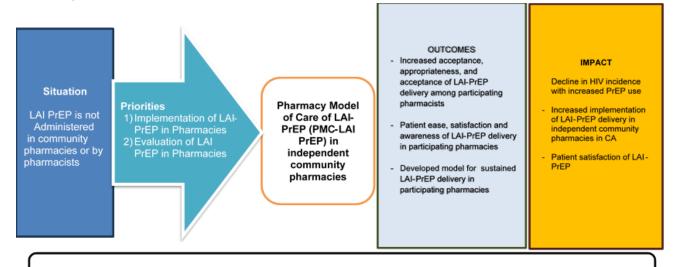






**Huntington Park** Los Angeles

Objective: This study facilitates the implementation of LAI and oral PrEP within the community pharmacy setting to increase access to these services and to inform policy and professional pharmacy practice in CA.



EVALUATION: REACH, EFFECTIVENESS, ADOPTION, IMPLEMENTATION, MAINTENANCE (RE-AIM)

Aim 1: Facilitate PrEP access and uptake in four CA pharmacies within high priority communities by implementing a pharmacy model for long-acting injectable PrEP that can be incorporated into each pharmacy's existing workflows and alight with current pharmacy business models.

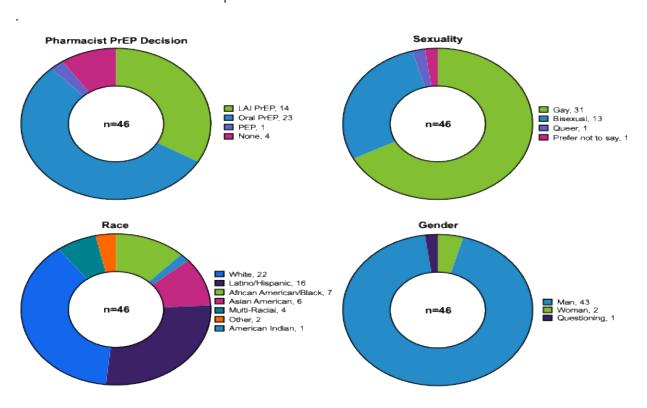
Aim 2: Evaluate the adoption, implementation, effectiveness, and reach of our model at independent community pharmacies.

#### **Timeline**



#### Results to Date

**Aim 1:** Three of the four community pharmacies have successfully implemented PrEP services and have enrolled 46 patients to date



**Aim 2:** Interviews of patient and pharmacist/staff perspectives about implementation of PrEP services have begun and expected to be completed in years 3 and 4.

## The FACTS Study: Field-Based Delivery of Long-Acting PrEP to Cisand Transgender Women at Elevated Risk for HIV in LA County





#### STUDY BACKGROUND



Access to sexually transmitted infection (STI) and HIV prevention services for women who may be exposed to HIV is challenging due to systemic inequities. The Los Angeles County (LAC) Division of HIV and STD Programs (DHSP) implements a field-based, mobile healthcare service for HIV/STI testing and STI treatment with these barriers in mind. UCLA is working with DHSP to integrate long-acting, injectable cabotegravir (CAB) PrEP into the van's existing services and evaluate this new program.

We believe the mobile health model for delivery of CAB is ideal for addressing challenges caused by inequity (i.e., employment, housing, insurance, marginalizing conditions) faced by women in Los Angeles.



#### STUDY TEAM AND COLLABORATORS

- Risa Hoffman Principal Investigator (UCLA)
- Shobita Rajagopalan Co-Investigator (LAC DHSP)
- Sonali Kulkarni Co-Investigator (LAC DHSP)
- Raphael Landovitz Co-Investigator (UCLA)
- Daisy Walker Project Manager (UCLA)
- Darlene Castro Research Assistant (UCLA)
- Andrea Kasowitz Research Assistant (UCLA)

#### **COMMUNITY PARTNERS**

- Homeless Outreach Program Integrated Care System (HOPICS)
- Downtown Women's Center (DWC)
- The Sidewalk Project (TSP)
- Maternal and Child Health Access (MCHA)
- Worksite Wellness



#### AIMS AND METHODS

## AIM 1 - Characterize uptake of CAB PrEP among women receiving field-based health services via a DHSP mobile health unit

- Women (cisgender and transgender) without HIV who are receiving services from the DHSP mobile health unit (n≈150) will be offered CAB PrEP; those who accept and are uninsured will be assisted with enrolling in Medi-Cal or other appropriate insurance plan so that they can receive CAB PrEP.
- All women offered PrEP will complete surveys (n≈150) and a subset will complete interviews (n≈30) so we can understand their interest in and barriers to HIV prevention services, HIV risk factors, and experience with the community-based as a model of care.

Current enrollment for Aim 1:

- Surveys (n=63)
- Interviews (n=4)

## <u>AIM 2</u> - Evaluate CAB persistence over one year among initiators

 Women who initiate CAB will receive ongoing visits from the mobile van for injections over 52 weeks and complete short follow-up surveys at each visit and a final survey so we can understand experiences with the community-based delivery model and barriers to remaining on CAB PrEP via the van over one year.

Current enrollment for Aim 2:

• CAB PrEP (n=4)

## <u>AIM 3</u> - Understand how to expand and sustain field-based mobile CAB PrEP delivery long-term

- Costs will be compiled over duration of the study, and endline in-depth interviews will be conducted with stakeholders from community partners
- Lessons learned will be disseminated broadly to inform HIV PrEP policies.

To date, our surveys show high interest in CAB PrEP (57%) versus oral PrEP (25%) or no PrEP (17%), but actual uptake of CAB PrEP is low (6%). Loss to follow-up prior to starting CAB and challenges with MediCal are the most common reasons for low CAB uptake by participants with interest.









## **Project Overview**

Kim Koester, PhD, MA (PI) Orlando Harris, PhD, FNP Robert Williams Starley Shade, PhD Lara Coffin, MPH
Michelle Palomares

Janet Myers, PhD
Colbey Ricklefs, MD, MPH

**Purpose**: Breaking Barriers is an implementation science study that seeks to increase access to longacting injectable pre-exposure prophylaxis (LAI-PrEP) in Fresno and Sacramento counties.

#### **Specific Aims:**

Aim 1: Conduct a **formative assessment** to understand demand for and challenges related to LAI-PrEP implementation, access, and use.

Aim 2: Convene a **PrEP Navigator Advisory Board** to foster social interaction, build awareness about shared concerns & collectively generate solutions to bottlenecks in LAI PrEP implementation.

Aim 3: Implement and evaluate a **Learning Collaborative Model** specific to LAI PrEP implementation.



## Collaborators













**One Community Health** 





# Building Equitable Access to Injectable PrEP Conceptual Framework

#### Context & Inputs

#### Community Needs

- Epidemiology of HIV
- PrEP to Need Ration
- Social Determinants of Health
- Stigma
- Social Norms

Workforce Needs / Capacity

- Data Infrastructure
- QI Capacity
- Networks / Partnerships

Policy Environment

- Funding
- Payer Sources

#### Learning Collaborative Strategy to Build Capacity

Shared aim & equity lens; common measures Structured learning sessions & peer exchange Practice coaching; Plan–Do–Study–Act (PDSA) cycles Transparent data feedback & benchmarking



#### Mechanisms of Change

Capability building (Breaking Barriers Coaching) Peer diffusion & network effects Adaptive problem-solving & rapid learning Mutual accountability & psychological safety



#### Implementation Outputs

Standardized HIV prevention workflows (screening, linkage) PrEP rapid-start pathways & persistence supports Task-shifting, role clarity, & referral protocols Integrated outreach & community partnerships

Short-Term Outcomes (6–12 mo)
Greater HIV testing
Improved LAI-PrEP awareness,
access, & uptake
Reduced time-to-PrEP initiation
Higher staff competence &



confidence

#### Longer-Term Outcomes (12-24 mo)

Increased LAI-PrEP persistence & adherence Improved linkage to prevention

services Reduced HIV incidence

Cross-Cutting Moderators

Community engagement; culturally responsive care; social supports (transportation, navigation); local context (policy shifts, workforce dynamics)



## Our Team in Action













## Contact

#### Community-based Assessment and Realignment for Long-Acting PrEP (CARE-LA) Project Summary

**PI:** Sheldon Morris, M.D., M.P.H., Department of Medicine, Division of Infectious Diseases, UCSD **Co-investigators:** Robert Bolan M.D. LALGBT, Ian Holloway PhD UCLA. Jessica Montoya PhD UCSD

Goals of the Project: The overarching goal of this proposal is to facilitate implementation and uptake of long acting injectable (LAI) HIV preexposure prophylaxis (PrEP), particularly among communities that have been less able to access PrEP due to structural, geographic, or other social determinants of health. The study will be performed over 4 years with implementation of LAI PrEP programs at diverse healthcare settings and pharmacies in Southern California, particularly those serving Black and Latinx MSM and transgender and/or non-binary individuals. This project includes a learning collaborative, which is a group of healthcare professionals from diverse healthcare settings and pharmacies who will convene to foster a collaborative learning environment to explore barriers and facilitators of LAI PrEP implementation and support the implementation of LAI PrEP. The UCSD Owen Clinic pharmacy's LAI PrEP program will be presented and one-on-one coaching will be provided to sites. We emphasize Black and Latinx MSM and transgender and/or non-binary persons during all phases of implementation to increase awareness of and demand for LAI PrEP in Southern California.

**Aim 1a:** Explore stakeholders' willingness and readiness to adopt LAI PrEP in diverse healthcare settings (e.g., community clinics, primary care clinics) and pharmacies through a learning collaborative.

**Aim 1b:** Engage Black and Latinx MSM and transgender and/or non-binary persons to understand community awareness of LAI PrEP and willingness and preferences for accessing LAI PrEP. **Aim 2a:** Develop blueprint for LAI PrEP deliver based on Owen Clinic LAI PrEP model as resources. Aim 2b: Identify community-engaged strategies for increasing demand for LAI PrEP to diffuse messaging on availability of LAI PrEP.

**Aim 3a:** Measure outcomes of LAI PrEP delivery at learning collaborative site over 1 year. **Aim 3b:** Survey Learning collaborative sites on LAI PrEP characteristics specifically about delivery of LAI PrEP to Black and Latinx MSM and transgender persons over time.

**Progress so far:** The learning collaborative group has been established, consisting of healthcare professionals from various settings. The team has successfully recruited participants, and started monthly meetings from January 2025. These meetings will continue to be tailored to the participants' needs and will support the ongoing assessment of their readiness to implement LAI PrEP. The meetings have included presentations for health department, Owen Clinic pharmacy, community pharmacies delivering LIA PrEP, ViiV healthcare (on Apretude), Gilead Sciences (on Yeztugo), and California government representatives.

The Community Advisory Board has been successfully established with 8-12 members representing clients from different implementing settings. The CAB is presented study updates and elicit feedback on the community opinions about the research and LAI PrEP. CAB meetings will continue to be held quarterly.

Currently the Clinical Research Coordinators (CRCs) have been trained on qualitative interviewing techniques and data collection protocols and have started individual key informant interviews and scheduled focus groups.

# **EXTRA MILE**

Extraordinary Methods to Implement Low-barrier care Experiences

Long-Acting Injectable PrEP for People Who Use Drugs



## STUDY OVERVIEW

**Goal:** To evaluate retention in care at 26 weeks among People Who Use Drugs (PWUD receiving Long-Acting Injectable Pre-Exposure Prophylaxis (LAI-PrEP).

Population: Adults 18+ who use drugs.

Approach: Clinical care and outreach using

Mobile Medical Units (MMUs) in collaboration

with community harm reduction partners.



## STUDY SITES

UCSD Owen Clinic and Mobile
Medical Unit operating across San
Diego County in partnership with
Eldorado Community Service
Centers and Harm Reduction
Coalition of San Diego.





## **RESEARCH TEAM**



Dr.Robert Deiss



Dr. Laura Bamford



Dr. Maile Karris

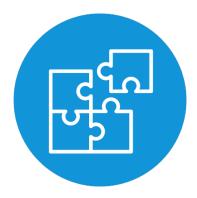


Dr. Angela Bazzı



Terence Hendrix

#### Clinical, Social, Behavioral, and Implementation Sciences



Portfolio: Measuring the Impact of Racism on the HIV Epidemic in California
2024 to 2026

PI: Nina Harawa – UCLA

PI: Moctezuma Garcia - SJSU

PI: Sean Arayasirikul – UCI

- 1. **Project Title:** Refining Measures of Medical Mis/Trust and Positive Coping for Racialized People Affected by HIV
- 2. Principal Investigator: Nina Harawa, PhD, MPH UCLA
- 3. Colnvestigators: Joanna Barreras, PhD and Laura Bogart, PhD
- 4. **Team members and Investigators:** Vasthy Amilibia, Frederick Ferguson, MD, MPH, Melissa Rios, MS, Jessie Robledo
- 5. **Key collaborators:** Bienestar Human Services, APLA Health, UCLA/CDU CFAR CAB, UCLA CHIPTS CAB, Bienestar Community Advisory Committee, Sean Lawrence, and Chandra Ford, PhD

#### 6. Study Goals

We are using audiorecordings from studies of two group-level interventions that were developed and tested by Dr. Laura Bogart and her team in order to carryout the following study aims:

- a. To qualitatively describe coping strategies, including medical mistrust and trust perceptions, related to intersectional stigma and discrimination (particularly racism), explore their positive and negative effects on HIV-related care-seeking, and delineate strategies used for successful HIV-related healthcare engagement by SMM Black and Latino men with and at-risk for HIV.
- b. To develop an item pool for quantitative scales in English and Spanish representing Informed Medical Mistrust and Trust (e.g., trust or mistrust in providers and treatments based on experience or reliable evidence) and Hazardous Medical Mistrust (e.g., mistrust-related avoidance of healthcare recommended tests and treatments).
- c. To modify and refine the item pool for future validation testing by eliciting feedback through focus group discussions with community experts on established, local community advisory boards.

#### 7. Progress to date:

- a. **Transcription**: Used AI to transcribe all 192 group intervention sessions from 24 different intervention cohorts. Had human beings review and validate transcription for 38 of these sessions (human review of transcripts against the audio). Half of all sessions were completed in Spanish, half in English. All were transcribed in their native language.
- b. **Summarization**: Developed, implemented, and improved upon prompts for summarizing all transcripts from the 192 group sessions using AI.
- c. Coding: Developed a codebook that captures 5 themes related to medical mistrust, medical trust, and coping. Continuing to work toward consensus in the coding of these transcripts after identifying inconsistencies across coders and refining our coding process.
- d. **Identifying survey items**: We reviewed the literature and identified 14 different unique published survey measures that examine trust and mistrust in medical providers and/or healthcare institutions. We began the process of mapping these existing survey items to findings from our transcript analysis. (Note: additional published surveys exist but they either overlap with these or are specific to specific health conditions or narrow aspects of the healthcare system.)
- e. **Community Engagement**: Have held 11 meetings with members of 5 different local HIV-related community advisory boards. We are meeting in an ongoing manner with the Bienestar, UCLA/CDU CFAR, and CHIPTS advisory boards.
- f. **Dissemination**: Drs. Harawa and Ferguson presented to the 2025 UCLA/CDU CFAR CAB conference in March 2025.
- g. **Training opportunities**: A UCLA MPH student completed an Applied Practice Experience with our team. Former, NCSP fellow and current UCLA Department of Family Medicine faculty member, Frederick Ferguson, MD, MSHS, has engaged in all of the coding processes, developed his own research project involving these data, and submitted a successful supplement to CHRP.

#### Working codebook for study

Main code	Subcode	Description	Examples
0 Gen. care access challenges	Access challenges not related to mistreatment	Negative experiences directly stemming from bureaucratic or overburdened systems (not mistreatment) that dissuade engagement	I asked for an emergency appointment but the first one they offered me was in 30 days, so I gave up.
1 Medical Mistrust	General	General feelings of distrust toward healthcare providers and institutions (providers, staff, hospitals, institutions) but not directly related to past experiences	I don't trust the healthcare system at all.
1 Medical mistrust	Past Experience	Expressions of mistrust that are rooted in specific negative experiences with the healthcare system that are not attributed to bias or discrimination or stigmaincludes vicarious experiences.	It happened with my therapist. You know, he had got all the background. I had become comfortable talking to him. All of a sudden, they lost their funding. He went somewhere else where they were funding. And I was just left hanging in the air. And then I had another therapist, which was a white guy, which he was okay. But I had just started bonding with this other guy.
1 Medical Mistrust	Potentially Hazardous	Avoidance of necessary health care due to mistrust (consider the action post avoidance and potential harm respondent's health).	I didn't go to the doctor because I don't trust their motives.
1 Medical Mistrust	Protective	Mistrust that leads to protective behaviors	I researched the medication before I took it.
1 Medical Mistrust	General Avoidance	Avoidance of necessary health care due to mistrust without clarity of whether or not it is hazardous, includes seeking alternative/holistic medicine/spiritual healing.	That's why we, you know, getting back to the subject of what we're talking about, we didn't take it to the psychiatrist or to the doctor. My upbringing was, we took it to the pastor.
2 Medical Trust	Trust in any aspect of medical care systems	General expressions of trust toward systems of care, individuals who provide healthcare, or specific treatments and preventives	I trust my doctor, so I always go back for check-ups.
3 Stigma	Racism/ethnic bias	Experiences of racial/ethnic discrimination in healthcare	I felt treated differently because of my race.
3 Stigma	Sexual Orientation	Discrimination or biased treatment based on sexual orientation	I was in there for something else, but when the doctor learned I was gay, she immediately ordered I get tested for HIV without asking me.
3 Stigma	HIV-related	Stigma experienced when seeking any type of HIV-related services	I felt judged when I asked about PrEP.
Stigma	Other stigma types, generally appears related (	Stigma experienced or perceived to be due to one's relative position in society based on one's access to resources, power, and prestige	homelessness, poverty/income/employment status/occupational prestige, weight, gender expression, language etc.
4 Engagement or disengagement	HIV-related services engagement	Participants engaged or disengaged in HIV services related to prevention (e.g., regular HIV testing) or treatment despite mistrust, or in the context of trust	I get tested regularly.
0 0	Non-HIV services-related engagement	Engagement, lack of engagement, or avoidance of healthcare services in the context of trust or mistrust	I test my blood pressure at home so I don't have to go to a clinic I don't trust.
5	Advocay	Any action that speaks in favor of, recommends, argues for a cause, supports or defends, or pleads on behalf of other and/or self, not specific to trust/mistrust.	One of the things is I no longer have an expectation that they're going to change overnight. But with {Organization}, I'm inside the system. So over a period of time, the change that I'd like to see can come about. But it's not going to come about instantly.  . But I'm going to a system and I can work within the system and they can figure out [how].









## Project COMPA

#### Comunidades Ofreciendo Más Prevenciones Agradables

Latino Hispanic, Spanish, 64

#### Participant Demographics

N = 66 (4 missing data) Mean Age 41 Identified as Indigenous n=27 Foreign Born n=58



37 26 3
Cis-Male Trans-Female Cis-Female
HIV- (32) HIV+ (24) UK (10)
Latino & Other, 2

Research Question: How does structural racism influence access to HIV testing, PrEP, and Treatment as Prevention (TasP) for Latinos in the Bay Area?

3 Focus Groups (n=30) were administered with Latinos who identified as a sexual minority, gender minority, or indigenous.

Individual interviews were administered with Latino service providers (n=15) and in the community (n=25) to gain an in-depth understanding of their lived experience.

#### **Qualitative Research Findings**

Racism from within as well as outside the Latino community has resulted in undocumented immigrants becoming hypervigilant and a preference for peer-based interventions that involve trusted social networks to promote culturally informed HIV services for the community.

HIV surveillance raised concerns about mistrust, confidentiality and privacy, especially among undocumented Latinos.

All participants thought **HIV contact tracing** is a good approach to engage people into HIV services, but emphasized that efforts **should increase transparency** (refer to back of page - handout) **and obtain consent from people.** 







# PROJECT COMPA

Comunidades Ofreciendo Más Prevenciones Agradables



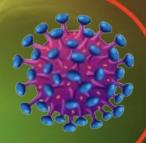
# Latinos Ending the HIV Epidemic

(1

Get tested & know your HIV status.



The public health department identifies your specific type of HIV for your well-being – HIV is unique – & they want to ensure you receive effective HIV medications and services.



The public health department monitors HIV cases – they identify HIV outbreaks to take care of you & promote healthy communities.



Trust Us! We contact people to enhance access to HIV treatment, PrEP, DoxyPEP, & other supportive services.









**Project Title:** Ballroom Has Something to Say! Geographies of structural racism and intersectional oppression and the House and Ballroom Community

**Principal Investigator:** Sean Arayasirikul, PhD (they/them), UC Irvine Joe C. Wen School of Population & Public Health

#### **Project Summary:**

While literature evidencing racial/ethnic disparities may be numerous, measurement that addresses the complex totalitizing nature of structural racism in relation to HIV-STI epidemics is conceptually thin. This study uses mixed-methods to examine how geographies and social spaces – as well as the policies and practices embedded therein - are racialized. All spaces are social; they involve people and practices; they hold meaning, carry history, transmit cultural norms and ideology, and provide critical context for understanding HIV-STI risk. This study seeks to understand how structural racism vis-à-vis communities' racialized geographies are enacted through social spaces, driving structural vulnerability among sexual and gender minoritized people of color (SGMPoC) inequitably placed at risk for HIV-STI infection. This study is intentionally and explicitly intersectional, operating on the notion that all oppressions are linked in a matrix of domination. As a result, although our focus will be to measure geographic and spatial determinants of structural racism, we will account for other structural oppressions specifically structural homophobia, cissexism or transphobia, sexism, and xenophobia and their intersections. The House and Ball Community (HBC) emerged in the 1970s as an underground sub-culture of SGMPoC to combat structural racism. Because the HBC is at the confluence of intersectional oppression, this study will not only further our understanding of HIV-STI vulnerability and anti-Black racism, but also racism and xenophobia that Latine HBC members face, as well as homophobia, transphobia, and misogyny that SGMPoC face. SGMPoC in the HBC have not only navigated racialized spaces out of survival, they have created spaces out of resilience for their own liberation.

Research Questions: (1) How do SGMPoC in the HBC experience structural racism through spaces and places? (2) How do geographic and spatial measures of structural racism impact structural vulnerability of SGMPoC in the HBC to HIV-STI transmission and their HIV-STI prevention, risk, and resistance behaviors and outcomes.

Specific Aims: Drawing from intersectionality and Pierre Bourdieu's conceptualization of social spaces, this study examines how geographies are racialized, and how SGMPoC in the HBC that reside in Los Angeles, Orange, Riverside, and San Diego Counties navigate them, creating new spaces for liberation.

- Aim 1: Develop formative geographic and spatial measures of structural racism.
  We will conduct in-depth interviews to develop preliminary geographic and spatial
  measures of structural racism. Participants will explore where structural racism is
  experienced, it's geographic, spatial, and historical characteristics, how they navigate
  this landscape, and the extent to which the group shares these experiences. For
  example, people may access/avoid certain spaces in a community (e.g. clubs/bars,
  street corners, pharmacies, HIV prevention services, clinics) due to structural racism.
- Aim 2: Contextualize the lived experience of structural racism in place, space, and society.
  - PhotoVoice is a participatory research method for transformational empowerment through critical awareness of one's feelings, behaviors and actions within their collective and social contexts. We will use PhotoVoice to characterize geospatial exposures to structural racism, how spaces and places are racialized in the social world, and what

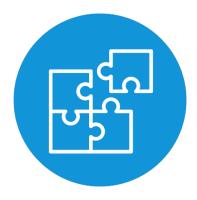
- resilience and survival strategies participants have developed as forms of resistance. Participants will photograph spaces that they have experienced structural racism directly or vicariously and describe how navigating these geographies impact their HIV-STI prevention, risk, and resistance behaviors and outcomes.
- Aim 3: Pilot and assess geographic and spatial measures of structural racism.
   We will conduct an ecological momentary assessment of real-time experiences of structural racism with SGMPoC in the HBC. Participants will receive assessments via mobile phone over 14-days. Geospatial and contextual data of structural racism reports and HIV-STI vulnerability and resistance practices and outcomes will be collected.

### **Progress:**

We are currently engaged in data collection for our qualitative phase (Aims 1 & 2). We have procured our license for our EMA platform and are test and pilot its programming and functionality. In our work with our wisdom council, community engagement, and critical reflection, we've identified a number of activities and products that are critical to supporting research with the HBC as meaningful partners. We describe these below:

- Wisdom Council Handbook: This document is a collaborative, living document that
  outlines roles and responsibilities for wisdom council members and their leadership role
  in the project and the collaboration. It situates these relationships in community engaged
  research, and is not just a product but a process of establishing group agreements and
  agreed upon practices.
- Structural Literacy Vignettes and Annotated Bibliography: One of the challenges we identified and struggle through is the complexity of discussing and examining geographic determinants of structural racism. Aside from the inaccessibility or scientific jargon, structural determinism as a core concept of structural racism is difficult to process. To address this, we created a set of vignettes to demonstrate how structural racism has shaped geographies and environments; and in turn, how these have impacted HIV-STI and lived experiences of SGMPoC in the HBC. We also created a brief annotated bibliography to translate peer-reviewed literature cited in our vignettes for lay audiences. These structural literacy tools are needed to ensure participants' understanding of the research and for us to be mindful about in the interpretation and dissemination of our research activities.
- Informal Community Benefits Agreement: Experiencing powerlessness and disenfranchisement in relationships with public health institutions, academic institutions, and community-based organizations is common among HBC leaders. Conversations informed the need to draft a "bill of rights" that describe the capital and import of the HBC to traditional structures in society that hold power, and to set the stage for advocating for community benefit from these relationships and engagements. We're exploring the potential of community benefit agreements and what that might look like to help HBC leaders own their power.
- House and Ballroom Community Media Discussion Guides: Media is an integral part of the Ballroom culture. On one hand, ballroom culture is a motor of mainstream popular culture, yet crediting ballroom is a constant struggle that makes cultural appropriation common. We created discussion guides of two films, *Kiki* and *I'm Your Venus*, to encourage learning about the HBC with the general public, but more importantly, newcomers (or kittens) to the HBC to examine the HBC's cultural legacy. These discussion guides underscore fundamental root causes and social determinants that historically shaped (and continue shape) the lived experiences of the HBC across time.

### Clinical, Social, Behavioral, and Implementation Sciences



# Portfolio: Economic Justice Interventions to Address HIV and HIV Syndemic Factors in California 2025 to 2027

PI: Paul Wesson – UCSF

PI: WeiTi Chen – UCLA

PI: Erik Storholm – SDSU











# GI-BOOST: Guaranteed Income to Boost HIV Care Continuity and Suppression Post-Jail Release

**Objective:** To understand if providing guaranteed income for a limited time can help people who are living with HIV and recently released from jail to better connect to, and remain in, HIV care. We will also study payment timing and how receiving guaranteed income impacts other areas participant's lives.

### **Study Team:**

Paul Wesson, PhD- P.I, UCSF

Asa Clemenzi-Allen, MD, Co-I, SFDPH/UCSF

Sheri Lippmann, PhD, Co-I, UCSF

Michelle Nakphong, PhD, Co-I, UCSF

Graham Hinchcliffe, MS, Study Coordinator, UCSF

### **Collaborators:**

**John Luna**, Financial Capability Investment (Financial Mentoring)

**Community Financial Resources Team** (Focus Payment Card Provider)

Kari Lariz, Community Consultant

### **Methods:**

- 2-year pilot Patient Preference Randomized clinical trial
  - (Arm 1) 1 lump sum payment (\$6750) or
  - (Arm 2) 9 monthly payments (\$750/month) or
  - (Arm 3) Participant's choice
- Surveys at baseline, 5 and 9 months
- Qualitative Interviews with sub-sample and system partners
- Analysis of patient medical record data
- Optional Financial Mentoring Sessions
- Test preliminary efficacy of the intervention on improving HIV care outcomes (compared to historical controls from retrospective cohort)

### **Progress and next steps:**

- The study IRB was approved in July 2025
- Recruitment is due to begin in October 2025

### **Study Population (N=33)**



- Adults living with HIV
- Recent incarceration in San Francisco County Jail
- Low income
- English literate



### PROJECT CARE: CALIFORNIANS ACCESS TO RESOURCES FOR HOUSING AND ECONOMIC SECURITY TO PROMOTE HIV CARE

Study Team:















From left to right: Wei-Ti Chen (UCLA School of Nursing), Jury Candelario (APAIT SSG), Chengshi "Koh" Shiu (UCLA), Yuè Begay (APAIT SSG), and Rachel Arbing (UCLA)

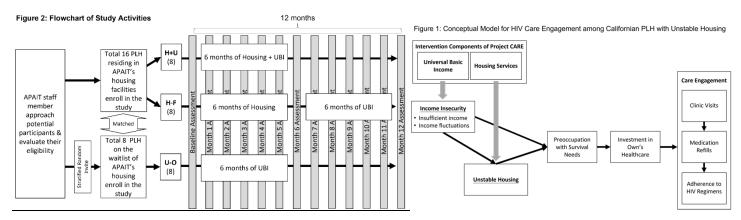
Project CARE is a two-year study that investigates the effect of unrestricted basic income (UBI) on health care engagement outcomes in people with housing instability and who are living with HIV. The clinical outcomes are defined as regular HIV clinic visits, HIV regimen refills, and adherence.

The study is a randomized-controlled, wait-list trial that will enroll a total of **24 participants** in Los Angeles. There are 3 groups of participants in the study:

**Group 1 (housing + UBI)**: Housing with APAIT plus UBI for 6 months. From months 6-12, stay in housing with APAIT with no income (follow-up is 12 months).

**Group 2 (housing-first)**: Housing-first with APAIT for 6 months. From months 6-12, receive a UBI plus APAIT housing (follow-up is 12 months).

**Group 3 (UBI-only)**: UBI only for 6 months. The UBI-only group is on the waitlist for housing services from APAIT. No housing services from APAIT or from other agency for the duration of study (follow-up is 6 months).



Study Aim 1: To test the preliminary efficacy of the intervention in enhancing care engagement among people living with HIV who are experiencing housing instability.

Study Aim 2: Assess the implementation outcomes of the three interventions among the participants, using both quantitative and qualitative data.

**Update on study progress:** The study has been UCLA IRB-approved, site visits have been carried out, and the manual of procedures is being fine-tuned. The obstacles encountered to date were distractions created by emerging federal policies (e.g., immigration raids, cuts to programmatic funding), identifying a method to assess capacity to provide informed consent and the ability to carry out study activities (i.e., money management), and identifying a UBI transfer method that does not limit participants in their type of spending. An amendment to the study protocol is required and once IRB-approved, we begin study recruitment this Fall.

# **Trans Wealth**





SDSU | San Diego State University

*Trans Wealth* is a program housed at the Trans Wellness Center (TWC) in Los Angeles that will provide guaranteed income to address economic and structural barriers that impede HIV care engagement (CHRP H25EJ9737). The program is led by bilingual members of the TGNB community and staff. Participants who meet eligibility criteria are enrolled in the program, randomized into receiving money either 1) in monthly installments or 2) a lump sum. Participants also receive financial advising from the Trans Economic Empowerment Project (TEEP), an ongoing program at the TWC that provides tailored economic empowerment services grounded in holistic, trauma-informed care. During this 6-month program, clients have three follow-up research visits (2,4,6 months) and unlimited TEEP visits.

### The *Trans Wealth* team:



Erik Storholm (PI)



Kimberly Ling Murtaugh



Sydney Rogers



Chloe Opalo



Carrie Nacht



Risa Flynn



Alex Dopp

+ County of Los Angeles, Poverty
Alleviation Initiative
+ community advisory board
+ providers to TGNB folx from

community organizations

### **Specific aims:**

- 1. Develop Trans Wealth into a trans-affirming, empowering, and person-centered guaranteed income intervention to complement the Trans Wellness Center's ongoing Trans Economic Empowerment Program (TEEP).
- 2. Conduct a pilot randomized comparative trial of the Trans Wealth intervention providing either a) 6 monthly payments of \$1000 or b) one lump sum payment of \$6000.

### Study progress: what have we done so far?

- Met with TWC community advisory board to inform study design
- Engaged with LA County's Poverty Alleviation Initiative and Guaranteed Income Coordinating Council
  quarterly meetings
- Learned from existing GI programs (LA County's BREATHE, DAP Health's Guaranteed Basic Income program, Flex Card Program for PLWH)
- Data gathering for GI payments: assessing benefits and drawbacks of various platforms (e.g., AidKit, MocaFi, GiveCard, checking account deposits)
- Coordinated "Trans Wealth Wednesdays" at the TWC for study enrollments, follow-ups, and TEEP programming visits
- Developed protocol for assessing impact on benefits programs and filing eligibility waivers
- Recruitment starting September 2025!



Email: sexualhealthequitylab@sdsu.edu | Phone: (619) 594-1139

# **Trans Wealth**





### **Enrollment**

- 30 TGNB participants will be recruited
- Participants must be living in poverty and/or unstably housed, living with HIV, and are virally unsuppressed at baseline
- Participants enrolled upon eligibility screening and baseline survey completion



### **Initial TEEP session**

- Conduct whole-person health and financial assessment
- Set employment, educational, and/or other goals
- Initial financial literacy and social service connection
- Schedule follow-up TEEP appointments



### Randomization

### **Monthly recurring**

- Recurring \$1000
   payments each
   month for 6 months
- TEEP financial and career services
- Social/structural service navigation
- Follow-up surveys and blood draws at 2, 4 months

### Lump sum

- One payment of \$6000 upon enrollment
- TEEP financial and career services
- Social/structural service navigation
- Follow-up surveys and blood draws at 2, 4 months

### Post-treatment assessment

- 6-month survey assessment
- 6-month blood draw
- HIV medication visit/pharmacy record review
- Resource utilization record review
- Evaluation of study outcomes

### **Components of TEEP**

 At the initial TEEP session, all participants will receive the "Trans Wealth 101" orientation to learn about expectations for the program, what kinds of services are available to them, and to select one of the three TEEP tracks that most align with their financial and career goals:







### Education & certification

### Job search

Entrepreneurship

- Participants are eligible for 1:1 counseling as well as group workshops that are specifically tailored to the track that they chose (e.g., resume building, financial literacy)
- The TEEP experience is completely customizable!

### Guaranteed income study testimonials from around CA:

"It has helped me pay off some bills, I'm building my credit, and I've also been able to put some money away for my grandson's college fund." "The first thing I did was run and pay my water bill. This additional income will also help me go back to school."

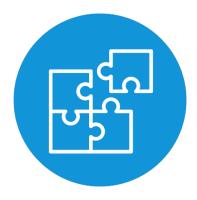


"It's a whole lot easier now to just work and feel like things are moving forward. It's a privilege because you definitely understand the responsibility that comes along with having something like this."



Email: sexualhealthequitylab@sdsu.edu | Phone: (619) 594-1139

### Clinical, Social, Behavioral, and Implementation Sciences



Portfolio: Social and Behavioral Intervention Pilot Studies to Support

HIV Prevention and Care

2024 to 2026

PI: Nicky Mehtani – UCSF

### A Pilot Clinical Trial of Ketamine-Assisted Psychotherapy for Methamphetamine Use Disorder & HIV Risk Behaviors





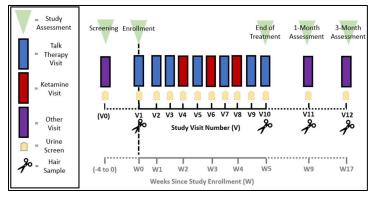


### **Primary Team Members & Collaborators:**

- Judy Tan, MPH Clinical Research Program Manager
- Iddoshe Hirpa, BA Research Assistant
- John Walker, NP Study Clinician
- Finn Black, RN Study Nurse
- Pierre Crouch, Psych NP Study Therapist
- Laya Jamali, LMFT Study Therapist
- Leticia Brown, LMFT Study Therapist
- Nicky Mehtani, MD Principal Investigator
- Mentors/Co-Investigators: Phillip Coffin MD, Mallory Johnson PhD, Brian Anderson MD, Jennifer Mitchell PhD



Methamphetamine use disorder (MeUD) is strongly associated with HIV transmission and accounted for over half of San Francisco's overdose deaths in 2021, yet no FDA-approved pharmacotherapies exist. Ketamine, an FDA-approved Schedule III medication with psychedelic properties, has demonstrated rapid antidepressant effects and promise in treating other substance use disorders by enhancing neuroplasticity and psychological flexibility. This pilot trial is the first to evaluate the feasibility, safety, and preliminary efficacy of ketamine-assisted psychotherapy (KAP) for publicly insured patients with MeUD who are living with or at risk for HIV. Conducted in partnership between UCSF and the San Francisco Department of Public Health, the single-arm trial delivers three weekly intramuscular ketamine sessions paired with seven trauma-informed motivational enhancement therapy

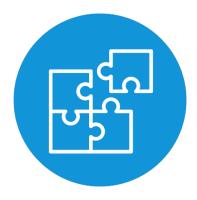


sessions, administered by community-based therapists experienced with the target population. Primary outcomes focus on feasibility, acceptability, and safety (e.g., enrollment, retention, adverse events), while secondary outcomes assess changes in methamphetamine use, HIV risk behaviors, cravings, and mental health symptoms. Findings will inform the design of a larger randomized trial and lay the groundwork for real-world implementation of KAP in safety-net clinical settings, with implications for HIV prevention and pharmaco-equity.

- Enrollment & Status: 21 screened; 11 enrolled (3 completed, 1 in follow-up, 5 in treatment, 2 withdrawn pre-ketamine due to health changes).
- Acceptability: Initial semi-structured interviews (n=3) suggest the intervention is well-received. Participants describe greater openness to talk therapy, reduced methamphetamine cravings, and view clinical dosing as mitigating risks of misuse.
- Challenges: Key learning points have included ensuring comprehensive understanding of the intervention at screening and balancing flexibility with feasibility to support structurally vulnerable individuals through multiple intensive visits.



### Clinical, Social, Behavioral, and Implementation Sciences



# Portfolio: Low Barrier Technology-Based Interventions for HIV Prevent and Care 2025 to 2026

PI: Angela Bazzi – UCSD

PI: Laura Bamford – UCSD

PI: Brittany Bryant – UCSF

PI: Susan Cassels - UCSB

PI: Indrani Choudhuri – Salk Institute

PI: Tommi Gaines – UCSD

PI: Thomas Martin - UCSD

PI: Stephanie Meyers-Pantele – UCSD

PI: Jennifer Nations – UCSD

PI: Tessa Rife-Pennington – UCSF

PI: Nadir Weibel – UCSD

# Expanding the Reach of HIV Prevention and Care through Harm Reduction Vending Machines

A CHRP-funded collaboration to advance low-barrier HIV prevention

# **Meet the Team**



Principal Investigator:
Angela R. Bazzi, PhD, MPH
(UCSD, School of Public Health)

## **Co-Investigators:**



Heather A. Pines, PhD, MPH (SDSU)

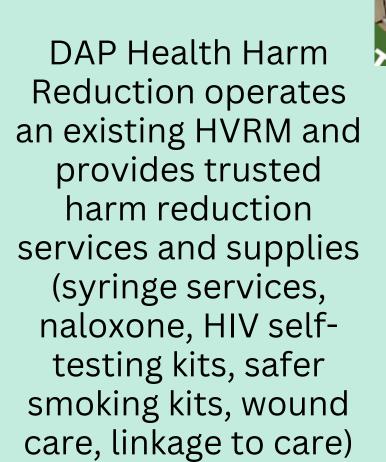
Erik D. Storholm, PhD (SDSU)





Tala Zoukari, DrPH, MPH (Training Role)

Neil Gussardo, MA DAP Health Harm Reduction Team (Palm Springs, CA)



6 days/week.



# **Background & Rationale**

HIV transmission among people who use drugs (PWUD) is a major challenge in California, intensified by opioid, fentanyl, and polysubstance use.

Barriers to facility-based HIV testing: stigma, homelessness, transportation, and competing priorities in syringe services programs (SSPs). Harm Reduction Vending Machines (HRVMs):

- Widely successful internationally, new in the U.S
- Provide syringes, safer smoking supplies, condoms, naloxone, and HIV self-test kits
- Offer anonymous, low-barrier access

### **Key questions:**

Are HRVMs feasible, acceptable, and equitable in underserved California communities?

# **Setting & Progress**

Project Period: March 2025- February 2026



### **Progress:**

- HVRM purchase is in progress
- Initial IRB approval obtained
- Preliminary analysis of existing HVRM data complete
- Manuscript in preparation

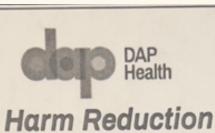
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College of Health and Human Services School of Public Health





# Why It Matters

HRVMs reduce stigma and expand HIV prevention for:

- People experiencing homelessness
- Diverse racial/ethnic groups
- Rural & tribal communities in EHE regions They advance HIV-ending goals through

equitable access and provide real-world lessons for scaling low-barrier interventions.

760.668.4872
760.508.4526
MOBILE OUTREACH:
Monday:10:30am-12:30pm
Call for locations
Tuesday: 10:30am-1pm
Methodist Church, Alejo & N.
Sunrise
Wednesday: 3pm-5pm
Call for locations
Friday: 9:30am-12:30pm
Arenas & El Segundo

FIXED SITE: 1445 N Sunrise Way Ste 102 Monday & Thursday: 8 am-7pm Tuesday, Wednesday & Friday:

8am-5 pm

# Expanding the Reach of HIV Prevention and Care through Harm Reduction Vending Machines

A CHRP-funded collaboration to advance low-barrier HIV prevention

# **Research Aims**

# Aim 1: PWUD Perspectives (n ≈ 30 interviews)

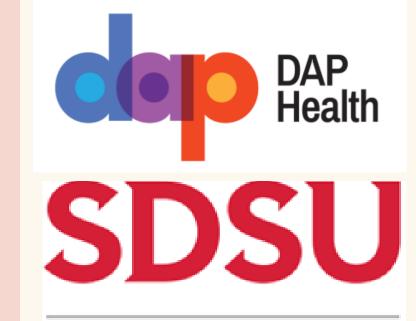
- Explore barriers/facilitators of HRVM use
- Identify preferred locations, supplies, and features (e.g., biometric ID, telehealth, data collection)
- Assess how HRVM access might encourage in-person engagement in HIV prevention and care

# Aim 2: Provider & Policymaker Perspectives (n ≈ 20 interviews)

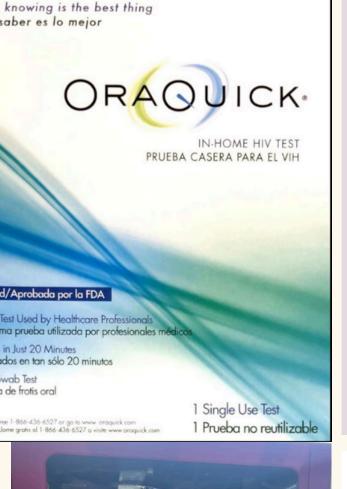
- Identify organizational and external determinants of HRVM implementation
- Explore resource needs, community acceptance, and political/funding constraints
- Assess acceptability of integrating new technologies (e.g., data tracking)

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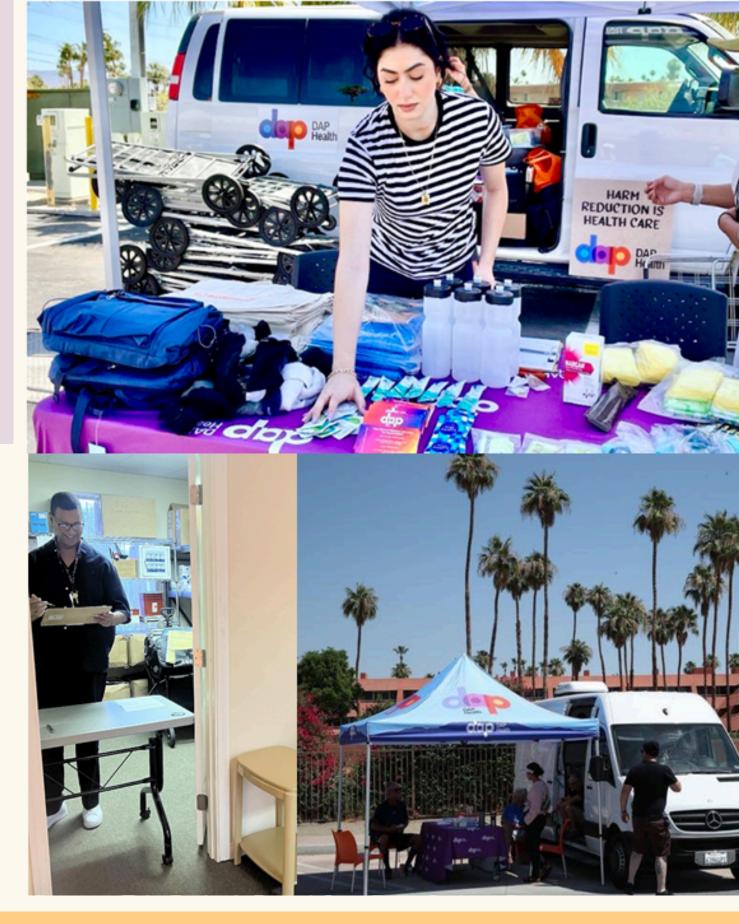
College of Health and Human Services School of Public Health



# **Exploratory Aim: HVRM Data**

- Compare demographics and supply distribution across two HVRMs (including HIV self-test kit uptake)
- Inform equitable expansion of services in Riverside & San Bernardino Counties







# **Funding**

CHRP award #H25TC8929S

# **Contact Information**

- Angela Bazzi (UCSD, PI)- abazzi@health.ucsd.edu
- Heather Pines (SDSU)- hpines@sdsu.edu
- Tala Zoukari (SDSU)- tzoukari@sdsu.edu

# Owen Low Barrier Mobile Clinic

Engaging People Who Use Drugs in HIV Care

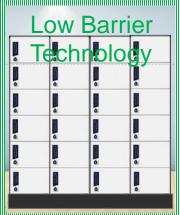
Low Barrier Strategies

Walk-in access to care, incentives, cross agency collaboration, low barrier care philosophy, and commitment to rapid modification









Study Overview Evaluate the acceptability, appropriateness, and feasibility of mobile HIV care, telehealth services, and medication lockers

Study Team: Laura Bamford / Thomas Martin / Jessica Montoya





# "SIHLEapp: Modernizing HIV Prevention for Black Adolescent Girls with Mobile Technology"

### **Project Overview**



The SIHLEapp project is funded by the California HIV/AIDS Research Program (CHRP). The project adapts Sisters Informing, Healing, Living, and Empowering (SIHLE)—an evidence-based HIV prevention program for Black adolescent girls—into a mobile application. The mobile format is designed to modernize the intervention, incorporate current HIV prevention strategies (e.g., PrEP, treatment as prevention), and increase accessibility and engagement for Black girls.

### **Study Staff**

Brittany Bryant (PI), Caravella McCuistian (Co-I), Jaime Smith (Research Manager), and Jennifer Le (Clinical Research Coordinator)

### **Project Aims**

- **Aim 1:** Explore preferred adaptation and implementation options of the SIHLEapp through qualitative interviews with Black girls aged 12–18.
- **Aim 2:** Explore potential targets for modernization of the SIHLE intervention through qualitative interviews with key stakeholders, including Black mothers or maternal figures and sexual health providers.

### **Progress to Date**

### Grant Setup:

- Successfully established the project infrastructure and budget.
- Hired key personnel, including a clinical research coordinator.

### IRB Approvals:

- Completed and received Institutional Review Board (IRB) approvals for provider and youth interviews.
- Developed consent/assent forms tailored for both youth participants and adult stakeholders.

### • Provider Recruitment:

- o Initiated outreach to community-based organizations and clinical providers who work with Black girls and families.
- o Conducted initial provider interviews, which take approximately one hour.

#### Youth Recruitment:

- Preparing for recruitment of Black adolescent girls to participate in interviews and provide feedback on SIHLEapp's design and content.
- Building partnerships with schools, community organizations, and youth-serving programs to identify participants.





### **Challenges & Adaptations**

- Provider recruitment has been slower than anticipated due to providers being overextended and experiencing high levels of occupational strain.
- To address this, we are adjusting our protocol and practices to better accommodate provider schedules and reduce the burden of participation.

### **Next Steps**

- Continue provider interviews and expand recruitment to a broader range of community and clinical settings.
- Launch youth recruitment and conduct interviews to inform culturally grounded adaptations.
- Begin app development and modernization process based on feedback from Black girls, mothers, and providers.

# Spatial optimization of dynamic low barrier HIV interventions for housing insecure sexual minority men in Los Angeles

California HIV/AIDS Research Program (CHRP) Conference 2025

**Study Goal:** To inform effective geographically-responsive low-barrier HIV prevention and care strategies for sexual minority men experiencing housing insecurity in LA county.

### Specific Aims:

- To map and identify geographic prevention and care deserts at a fine scale in LA county.
- To identify spatially-explicit demand for low-barrier technologies among sexual minority men in LA.
- To conduct a qualitative rapid needs assessment, so that beneficial low barrier technologies can be strategically placed across the county

#### Data & Collaborations

**mSTUDY** 

The data consist of 219 mSTUDY participants. The mSTUDY was a NIDA-funded longitudinal cohort of mostly Black and Latinx sexual minority men (SMM) living in LA (**PI: Gorbach**). Location data include: residential, socialization, sex acts, substance use, primary care physician, pharmacy, last HIV test, and last STD test.

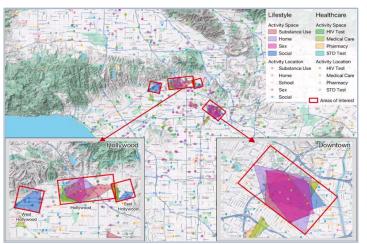


Fig. 1: A map illustrating the spatial pattern and overlap of activities and their associated activity spaces among mSTUDY SMM in LA. (Cassels et al, 2025: Health & Place)

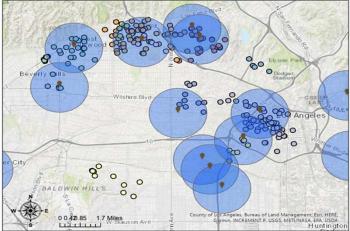


Fig. 2: A map representing a sub-set of individuals within and outside of a 1-mile buffer of pharmacies in LA. These types of data can be used to optimize locations of HIV services.



**Long term goals**: Demonstrate a <u>user-friendly</u> and easily <u>modifiable</u> methodology to identify where people go, where various low-barrier HIV prevention methods are located, and identify places and populations with barriers to access.

Susan Cassels, Terrell
Winder, Gabrielle Husted
University of California
Santa Barbara







- a. **Project Title:** Software for Precision HIV Therapy: Leveraging Genomics for Enhanced Drug Resistance Prediction
- b. **Team:** This project builds on work initiated by Dr. Avik Biswas in Dr. Ronald Levy's lab and further developed with Dr. Choudhuri. Dr. Biswas, now a postdoctoral fellow at UC San Diego and Schmidt Al Fellow co-mentored by Dr. Lyumkis, will serve as a Co-I. Dr. Choudhuri, now a staff scientist in Dr. Lyumkis's lab, is spearheading the effort as Applicant PI, with Dr. Lyumkis as Mentor. Drs. Lyumkis also maintains jointly funded R01s (U54-Al150472, U54-Al170855, U01 Al136680, R01 Al178849) with Ron Levy (Our collaboration at the Temple University) that provide complementary data and cost-sharing. Other notable collaborators include Eric O. Freed (NCI/NIH), who contributed his expertise in virology, and Andrej Sali (UCSF), who provided insights into structural biology. The proposal supports development of novel, accessible software for patient-specific drug resistance monitoring and funds Dr. Choudhuri's tenure at the Salk Institute. Add collaborator.

### c. Abstract, Scientific Aims & Progress:

Abstract: Antiretroviral therapy (ART) has transformed HIV/AIDS care, improving viral suppression, transmission prevention, and patient health. Yet drug resistance, including to the latest ART, remains a growing challenge. Whether a drug-resistant mutation (DRM) persists depends on the tradeoff between resistance and viral fitness, which is strongly influenced by the genetic background in which the DRM arises. We and others have shown that the fitness effects of primary DRMs vary widely across patient populations due to epistatic interactions, making laboratory-derived HIV clones (e.g., NL4-3, HxB2, LAI IIIB) poor proxies for patient-derived viruses. Current methods for assessing patient-specific DRM effects still rely on such clones, limiting clinical accuracy. To address this, we propose a machine-learning-based, lightweight software tool that predicts the fitness impact of DRMs within individual patient sequence backgrounds. Leveraging large-scale patient data from the Stanford and Los Alamos HIV databases, the tool will provide an accurate and accessible platform for predicting resistance and guiding tailored treatment strategies. Ultimately, this approach could bridge the gap between laboratory predictions and real-world patient needs, improve treatment efficacy across diverse populations, and expand access to cost-effective DRM testing, particularly in underserved settings.

**Specific Aims:** We propose to develop an Al-based tool to predict patient-specific DRM fitness effects and extend drug-resistance testing to underserved communities.

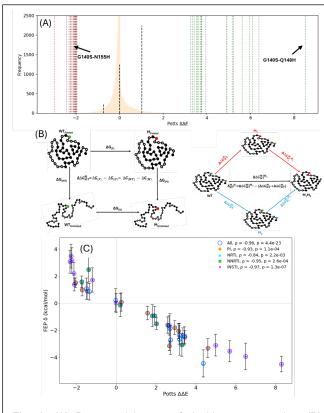
### Aim 1: Develop and implement ready-to-use software for predicting the effects of patient-specific HIV drug resistance

Current drug-resistance testing relies on introducing patient-derived resistance mutations into standard HIV clones (NL4-3, HxB2, LAI IIIB) and measuring fitness, but these often fail to capture patient-specific variation. Building on our prior Potts (Boltzmann machine learning) model work, we will develop AI-based software trained on large HIV sequence datasets (Stanford, Los Alamos) to predict DRM fitness across diverse patient backgrounds. The user-friendly tool will provide patient-specific predictions that improve on clone-based testing and guide optimal treatment selection.

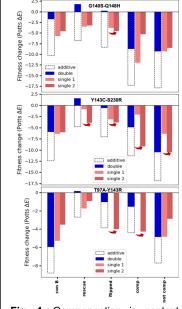
### Aim 2: Validation and comparison of software predictions with fitness data

We will validate the software's predictive capabilities through fitness experiments using patient-derived HIV sequences, ensuring its accuracy and reliability. We will leverage experimental fitness data available in the literature as well as single-round replicative capacity measurements carried out in house, which can be performed in high-throughput. The validations will be used as feedback to enhance the model's predictive power. These evaluations will demonstrate the software's potential to enhance the precision of HIV drug resistance testing, support personalized therapy, and guide future improvements to ultimately advance the management of HIV drug resistance.

**Progress:** We applied Potts statistical energy machine learning models to people living with HIV (PLWH) -derived HIV sequences and found that DRM fitness effects vary widely by the sequence background often contrasting with results from standard molecular clones (NL4-3, HxB2, LAI IIIB) prediction. (**Fig. 1**) In recent work<sup>1</sup> that is now available as a preprint, we identified the networks of synergistic and antagonistic epistatic pairs (**Fig. 2A**), including clinically observed combinations (e.g., G140S–Q148H) and novel pairs, providing a foundation for resistance prediction and therapy design. Using extensive (~100) free energy perturbation molecular dynamics simulations (**Fig. 2B**), we found that pairwise epistasis largely stems from cooperative effects on protein stability and folding. These effects strongly and significantly correlate with Potts model predictions of fitness epistasis (**Fig. 2C**), demonstrating that evolutionary sequence data reliably predict structural impacts of mutations.<sup>1</sup> This establishes the Potts model as a powerful "scanning"



**Fig. 2**: (A) Potts model scan of double mutant cycles. (B) Thermodynamic cycles of Mutational free energy calculations. (C) Correlation between structure-based FEP/MD and evolutionary sequence-based Potts model.



**Fig. 1**: Compensation is context dependent: Phenotypes can change depending on the sequence background. Shown in panel is HIV Integrase.

reinforce a mechanism of resistance evolution whereby viruses escape drug pressure selectively engendering mutations at "intrinsically" coupled sites, allowing them to cooperatively ameliorate fitness detriments incurred by individual drug-resistance mutations. This work enables us to predict which target protein residues might evolve resistance mutations based on the premise (supporting Aim 1) supported by our work that DRMs evolved at strongly intrinsically coupled residue positions offering the virus viable escape pathways through co-operative mutations that ameliorate fitness detriments of individual DRMs. We aim to further enable this as an additional feature in our software. In further ongoing work, we have been able to dissect the background dependence of strongly coupled "primary and accessory" mutation pairs. We find that the vast majority of "primary and accessory" mutation pairs in the HIV literature identified based on specific molecular clones of the wild-type virus can switch roles in patient-derived

sequences, carrying implications for how drug resistance can evolve differently in PLWH. Latest finding revels that E138K/G140A/Q148R triple mutant reduces Cabotegravir (latest NIH approved drug) potency by ~380-fold through cooperative epistasis<sup>2</sup> that destabilizes the integrase active site, supporting our aims by highlighting how patient-specific sequence backgrounds and coupled mutations critically alter DRM fitness. These advances establish a validated computational framework to develop and test our proposed AI software for personalized HIV drug resistance prediction.

tool

and

The

for

development

mutational epistasis

predictive software

(supporting Aim 1).

collectively

supports

probing

into

results

#### References

- 1. Biswas et al. (2025), Evolutionary Sequence and Structural Basis for the Epistatic Origins of Drug Resistance in HIV. BioRxiv. DOI: 10.1101/2025.04.30.651576
- 2. Choudhuri et al. **(2025**), Structural and mechanistic insights into cabotegravir resistance in HIV-1 integrase. Biophysical Journal, 124, 3, 176a 177a. DOI: 10.1016/j.bpj.2024.11.1006

# LOW-BARRIER ACCESS TO HIV PREVENTION AND HARM REDUCTION FOR TRIBAL COMMUNITIES

Tommi Gaines, DrPH (Navajo/Hopi; UCSD) Christina Perry, MPH (Wellness Center Program Manager)

# Most Community Members Prefer Home-Based HIV/STI Testing



To advance health equity, our academic team partnered with a Southern California Tribe to explore integrating HIV self-testing into the Tribe's Wellness Program. Most community members preferred non-clinic testing, and nearly half expressed interest in accessing self-test kits through the program.

The Tribe previously installed a public health vending machine (PHVM) with naloxone and fentanyl test strips. In its first year, the PHVM was used over 100 times, demonstrating strong community engagement. Next, the Tribe will launch an interactive touchscreen vending machine offering HIV, chlamydia, and gonorrhea self-test kits along with other services. Unlike the current PHVM, the new machine will also provide on-demand training, care referrals, and anonymous data collection.



### Specific Aims

Using a community-engaged approach, we will conduct a formative evaluation to examine what happened during the first year of implementing the interactive touchscreen vending machine (Aim 1: utilization patterns) and why it happened (Aims 2-3: contextual assessment of the implementation process).

### Machine Learning to Enhance HIV Data-to-Care

Research Team



Ravi Goyal PhD



Thomas Martin MD



Susan Little MD



Sanaz Nazari PhD

### **Background**

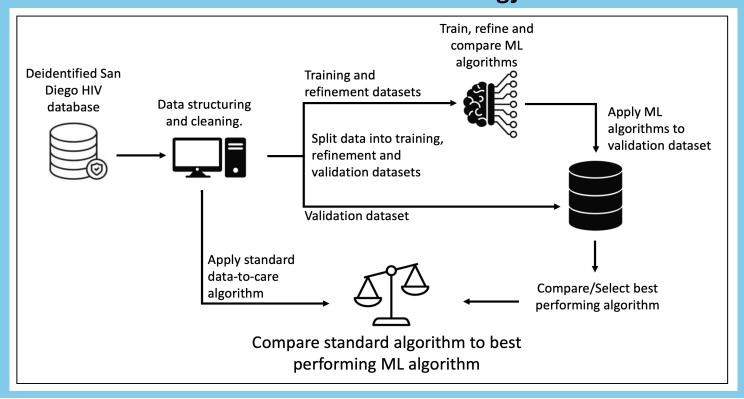
Public health data-to-care use routinely reported HIV care data to identify people who may be out of care. However, existing algorithms are highly inaccurate and reactive by nature leading to delayed and wasteful resource allocation. We hypothesized that using machine learning could improve the existing algorithm

# Research Questions

Can behavioral information contained within historical longitudinal viral load and CD4 data improve prediction of future unsuppressed viral load?

Can machine learning improve the accuracy and time-toidentification of HIV data-to-care?

### **Research Methodology**



### Results

Behavioral information contained within longitudinal HIV viral load is predictive of future unsuppressed viral load

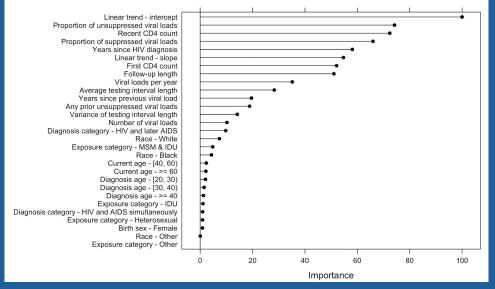
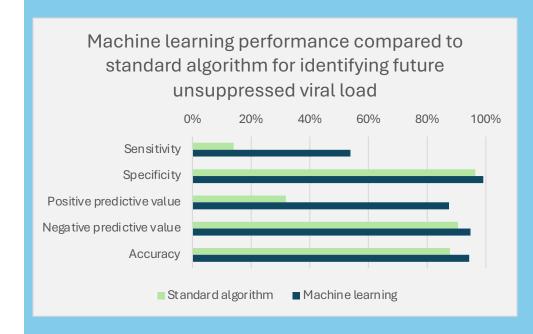


Figure showing relative variable importance performed by random forest method for prediction of future unsuppressed viral load. Viral load predictors ranked higher than 'traditional' risk factors for predicting future unsuppressed viral load.



Machine learning improved the sensitivity and specificity of datato-care algorithms. The proportion of people flagged for outreach that would have a future unsuppressed viral load was improved from 32% to 88%

Over a 1-year evaluation period, switching from the standard algorithm to machine learning HIV data-to-care would correctly identify an additional 1412 individuals with future unsuppressed viral load and save a potential maximum of 353 person-years of viremia

Acknowledgements: We are most grateful for CHRP research grant funding for enabling this project

Publications: Ravi Goyal, Gordon Honerkamp-Smith, Alan Wells, Susan J Little, Thomas CS Martin. Predictive models to identify individuals with HIV at risk of unsuppressed viral load using routine public health data. *JAIDS* 2025;99(4): 325-333

# EXPLORING THE FEASIBILITY & ACCEPTABILITY OF HARM REDUCTION VENDING MACHINES IN ORANGE COUNTY, CA

Orange County had the 2<sup>nd</sup> highest rate of overdose deaths in the state in 2020 and has been designated an Ending the HIV Epidemic priority jurisdiction. Harm Reduction Vending Machines are a relatively low-cost, low-barrier, technology-based tool that can expand access to life-saving supplies. Research is needed, however, to determine whether these vending machines would be viable in Orange County's unique sociopolitical context - and if so how they can be designed to best serve people in the county.

Aim

To assess attitudes towards, and suggestions for, harm reduction vending machine among people who use drugs and key stakeholders (e.g., service staff, health care professionals, law enforcement, and/or people involved in local politics/government) in Orange County.

### THE STUDY TEAM



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Peter Davidson, PhD
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University of California, San Diego





Recovery Road
Nonprofit | Community Collaborator
Recovery Center, Naloxone Ambassador, Food Bank,
Housing Navigation
Anaheim, California

# EXPLORING THE FEASIBILITY & ACCEPTABILITY OF HARM REDUCTION VENDING MACHINES IN ORANGE COUNTY, CA



### STUDY METHODS

### Qualitative Interviews

- We are conducting 40-60 in-depth interviews.
- Interviews last 30-60 minutes.
- Interviews are then transcribed for rapid thematic analysis.

### Target Population: People Who Use Drugs

- 18 and older
- Orange County resident
- At least weekly use of stimulants and/or opioids
- Meets CDC HIV transmission risk criteria

### Target Population: Key Stakeholders

- 18 and older
- Works at an Orange County organization at least part-time.
- Worked at organization for at least 6 months

### PRELIMINARY FINDINGS

### Potential locations



**Parks** 



**Transit Stations** 



Clinics & ED's



Libraries



**Bars & Clubs** 



**Shelters** 



Universities

## Vending machine acceptability will likely depend on the city/location of their placement:

"Just depends on where they are. And where they're placed. Again, there's definitely folks in this area that have particular views on certain things... So yeah, I think it would be finding a balance between the two."

(Zack, Healthcare Professional)

## Syringes & safer use kits are likely not going to be feasible in Orange County:

"But once you have those needles, then that's the single item where, even if we see that the studies do indicate that having access to clean needles has a positive impact, that has been very difficult to go and implement."

(Manny, Local Politics)

### **Potential Materials**



Naloxone



**Condoms** 



HIV/STI Self-Test Kits



Hygiene Kits



**Wound Care** 



**Pregnancy Test** 



**Items for Joy** 

### STUDY GOALS & FUTURE DIRECTIONS



Goal

To leverage the findings of this study to secure additional grant funding to develop and pilot these vending machines (or a similar public health intervention) in Orange County

# Low Barrier Technology Implementation at Safe Sleeping Sites for People Experiencing Homelessness

### Team members

Jennifer Nations, PhD (PI), Stacey Livingstone, PhD, Ken Saragosa, Jessica Jatiram, Jenna Rose, Kuni Stearns, Crystal Yang, PhD, and Haven Lo.

Research Lab: UC San Diego Homelessness Hub

### **Key collaborators**

Healthcare in Action – a mobile health clinic, Dreams for Change – a homeless service provider, Downtown San Diego Partnership – a homeless service provider and advocacy organization for property owners.

### Overview

Unhoused individuals have poorer HIV health outcomes, perpetuating disparities in California even as the HIV epidemic slows in the state. These findings suggest that current strategies for ending the epidemic, including the use of low-barrier technologies for prevention and treatment, are not reaching unhoused individuals at the same rate they reach those with stable housing. Unhoused individuals face daily challenges to meeting basic needs that make HIV prevention and treatment a last priority. Continual displacement of unsheltered homeless people further disrupts their ability to access care: encampment sweeps lead to the loss of belongings and create literal and relational distance between healthcare providers and clients, both of which can disrupt access to HIV interventions.

Safe sleeping, or sanctioned encampment, sites may minimize the disruption in access to HIV technologies. Such sites provide individuals with a place to sleep without fear of being ticketed, pushed out, or arrested. Safe sleeping sites are low barrier, meaning that individuals do not need identification to enter and do not need to adhere to sobriety rules (although they cannot use substances on-site). Clients can access a range of services, including showers, laundry, food, and medical care. Because safe sleeping provides individuals with a settled location, they may be an important site for mobile health services and facilitate the implementation of low barrier technology HIV interventions, including the use of medication adherence phone apps, vending machines for HIV testing kits, or safe boxes for storing belongings.

This study takes place in the City of San Diego. San Diego is one of 50 jurisdictions that account for more than half of all new HIV diagnoses in the U.S. High transmission rates in the city may in part be connected to the high volume of people experiencing homelessness. San Diego opened two safe sleeping sites in October 2023 after the city policymakers banned homeless encampments in public places.

We are assessing whether a safe sleeping intervention provides adequate conditions for other low barrier interventions, aimed at reducing HIV transmission, to succeed. Our work is timely, because

current encampment bans exacerbate infectious disease risks and interventions like safe sleeping could be key to facilitating individuals stay connected to services and interventions.

### Specific Aims & Progress to Date

Aim 1. To strengthen the partnership between UC San Diego's Homelessness Hub and local service providers hired by the City of San Diego to administer safe sleeping program. Strengthening these partnerships will facilitate future implementation of recommendations that emerge from our study. We have successfully formed partnerships with three agencies and are in the process of connecting with two others.

Aim 2. To center the lived-experiences of unsheltered individuals to understand whether safe sleeping can improve access to low-barrier HIV technology. We will do this using a comparative method wherein we interview people experiencing homelessness who stay in safe sleeping sites and people who do not. We also accomplish this by having three people with lived experience of homelessness and two people with HIV on our research team.

Aim 3. To investigate interest in, acceptability, and feasibility for using different technology applications at safe sleeping sites, including vending machines and safe boxes. We will do this by interviewing clients at safe sleeping sites, people with experience of homelessness who are HIV+, interviewing staff, and shadowing service providers and mobile clinic providers. We have conducted 49 interviews with clients of the City of San Diego sanctioned camping program. Questions addressed rapport and trust with mobile clinic providers, HIV prevention strategies, and ease of access to medical care and HIV prevention tools. We have shadowed providers of one mobile clinic and one homeless service organization.

### **Preliminary Findings**

1) strong trust in mobile clinic providers; 2) participants' desire to retain medications on their person due to safety concerns; 3) misconceptions about HIV treatment and transmission.

Nearly all participants reported trust in mobile clinic providers attributable to consistency in care access in a settled location. Participants were unable to identify high-risk behaviors associated with transmission of HIV such as unprotected sexual intercourse, substance use, same-sex intercourse, and multiple sexual partners. Participants reported that keeping their medications on them fostered greater autonomy and facilitated better adherence.

Our findings suggest that mobile clinic providers are well-positioned to eliminate misconceptions about treatment and prevention while providing medically accurate HIV care. Future directions in our work will examine HIV-specific care in participants with HIV to assess treatment accessibility among unsheltered populations.



### Low Barrier Technology Interventions for HIV Prevention and Care

Funded by California HIV/AIDS Research Program (CHRP)



### San Francisco VA Health Care System (SFVAHCS) Harm Reduction Program Objectives

The SFVAHCS Harm Reduction Vending Machines (HRVMs) aim to increase access to essential harm reduction supplies and services through innovative, 24/7 accessible vending machines. This program addresses barriers to traditional service delivery by providing free, anonymous, stigma-free access to life-saving resources for individuals who use substances, particularly among underserved populations including Veterans experiencing homelessness.

### **CHRP Funded Objective & Specific Aims**

**Primary Objective:** We aim to stock 900 HIV self-tests (HIVSTs) in 15 HRVMs currently used by over 600 Veterans in urban, suburban, and rural Northern California. We will then use the RE-AIM Model for evaluating individual and organizational factors which determine public health impacts of a program or policy.

### **Specific Aims:**

- **AIM 1-REACH:** Characterize HIV risk factors among Veterans with VM-dispensed HIVSTs, focusing on men who have sex with men, sex without barrier method, and unregulated drug use
- AIM 2 EFFECTIVENESS: Determine if HRVM-dispensed HIVSTs improves Veteran access to HIV resources, leading to increased testing, diagnosis, and follow-up care
- AIM 3 ADOPTION: Identify which HRVM locations achieve highest HIVST access, anticipating greatest utilization at 2 supportive housing sites and 1 outpatient clinic
- AIM 4- IMPLEMENTATION & MAINTENANCE: Evaluate patient-reported outcomes including acceptability, convenience, privacy, satisfaction, reduced stigma, and preference for HRVM-dispensed HIVSTs

**Supplement Focus:** We will describe the experiences and perspectives of 15 Veterans who accessed and used a HIVST dispensed via SFVAHCS (San Francisco VA Health Care System) harm reduction vending machine by conducting qualitative interviews and conducting a thematic analysis.

### **Project Status & Timeline**

- August 2023: Program launch 15 HRVMs deployed across 7 California cities
- ✓ February 2025: IRB submission (parent grant)
- ✓ April 2025: IRB submission (diversity supplement)
- ✓ August 2025: IRB approval obtained from UCSF and SF VA
- ✓ Next steps:
  - ❖ Fall 2025: focus groups with Veteran Advocates; HIV self-test deployment into HRVMs; data collection; methodology manuscript submission
  - Winter 2025: interviews with Veterans who utilized HRVM-dispensed HIVST; data analysis
  - Spring 2026: conference abstract and manuscript preparation and submission

### **Research Team**



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### **CHRP Grantee Meeting 2025 Abstract**

Beyond the Sticker Price: Comprehensive Cost Analysis of Harm Reduction Vending Machines in VA Settings
Wendy Xie, BS<sup>1</sup>; Michael Douglas, MS<sup>1</sup>; Tessa Rife-Pennington, PharmD, BCGP<sup>1</sup>,<sup>2</sup>

School of Pharmacy, University of California, San Francisco; <sup>2</sup>San Francisco VA Health Care System

**Introduction:** Harm Reduction Vending Machines (HRVMs) improve access to supplies such as syringes and condoms yet have not been widely implemented within the United States. This project evaluated implementation and maintenance costs for 15 HRVMs.

**Context/Background:** In August 2023, the San Francisco Veterans Affairs Health Care System launched 15 HRVMs: 2 in a hospital, 7 in community-based outpatient clinics, and 6 in Veterans supportive housing buildings across 7 California cities.

**Results/Outcomes:** During the 22-month period, HRVM access cards were issued to 611 Veterans. Total cost was \$356,165.03. A total of 16,658 products were dispensed. The comprehensive program cost per item was \$21.38, with \$19.63 (91.8%) for operational overhead and \$1.75 (8.2%) for supplies. Housing/residential sites achieved \$15.41/product compared to \$29.04/product at healthcare facilities.

### **Key Findings:**

- HRVMs reached > 600 Veterans and dispensed > 16,000 products across VA and housing settings
- Most costs were attributable to staff salary and HRVM procurement
- Cost transparency can inform future expansion and budgeting

#### Recent peer-reviewed publications:

- **Rife-Pennington T**, Vu T. Harm Reduction Services for Veterans in Supportive Housing: A Pharmacist-Led, Interdisciplinary, Street-Medicine Approach. *INNOVATIONS in pharmacy*. (in press)
- **Rife-Pennington T**, Dinges B, Vu TT, **Douglas MP**, Pennington DL. The Missing Dose: Integrating Harm Reduction into Pharmacy Curriculums. *Subst Use Addctn J*. Published online July 10, 2025. doi:10.1177/29767342251351753.

#### **Upcoming conference presentations:**

- Rife-Pennington T, Apana N, Douglas M. "This is a Great Idea." Harm Reduction Vending Machines in Veterans Supportive Housing. 2025 AMERSA National Conference. Runner-Up, Best Research Abstract Award.
- Ruggles A, Tietjen D, Aguirre E, **Rife-Pennington T**. Incorporating a Veteran's Living Expertise of Sex Work and Substance Use into Clinician Education. 2025 AMERSA National Conference.
- Apana NK, **Xie W**, **Douglas M**, **Rife-Pennington T**. Evaluating the Impact of Harm Reduction Vending Machines on Supply Distribution: A 23-Month Pre/Post Evaluation. 2025 SFBayCRN/IMPACT Annual Meeting.









## **ConversHIVe**

# Decreasing Implicit Bias in HIV Prevention and Care Teams through Al-based coaching



Nadir Weibel, PhD

Computer Science and Engineering + Design Lab

UC San Diego

Principal Investigator



Robert Deiss, MD

Division of Infectious Diseases + Owen Clinic

UC San Diego

Co-Investigator



Manas Bedmutha, MS
Computer Science
PhD. Student



Chen Chen, PhD Computer Science PhD. Student



Nishanth Chidambaram, BS Computer Science MS Student

### **Specific Aims**

We integrate Generative AI and Large Language Models (LLMs) to create **ConversHIVe** a rapid simulation and feedback application deployed as an AI-driven web interface able to train HIV treatment and prevention teams in effective, unbiased communication.

### Simulated Patients with Generative Al

We use large language models (LLMs) and generative speech tools to create dynamic, voice-interactive patient personas. These Al-driven agents represent diverse backgrounds and symptoms, allowing staff to practice real-world scenarios in HIV care and prevention. Personas are co-designed with the UCSD Owen Clinic and the AVRC Community Advisory Board to ensure authenticity and relevance.

### Multimodal Communication Sensing

We combine AI models that analyze verbal language (via transcripts and LLMs) with models that sense nonverbal behavior to capture the full picture of patient-provider interaction. Our analysis is grounded in the UNBIASED dataset of over 100 real clinic visits, including visits with people living with HIV (PLWH), to train and evaluate AI systems that understand social signals and provider empathy

### Actionable Feedback via ConversHIVe

ConversHIVe integrates these technologies into a voice-chat training tool where users talk with simulated patients and receive real-time, Al-generated feedback on communication quality, empathy, and behavior. The system helps users reflect, improve, and build trust in high-stakes clinical settings.

# UC San Diego

### Why ConversHIVe?

People living with HIV (PLWH), especially from marginalized communities, often face stigma, discrimination, and communication barriers in healthcare settings. Implicit bias—based on race, gender, sexual orientation, or substance use—can limit access to prevention and treatment services. We are creating ConversHIVe to directly address these challenges by training care teams to recognize and overcome bias during real-world interactions.



### What Is ConversHIVe?

ConversHIVe is a web-based training tool that simulates patient-provider conversations using advanced Al-generated virtual patients providing real-time feedback on communication quality, empathy, and implicit bias.



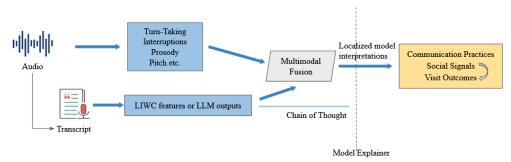




Developed in collaboration with the UCSD Owen Clinic, the AVRC Community Advisory Board, ConversHIVe will help teams practice and improve communication in a safe, supportive environment.

### **How It Works**

- Practice: Clinicians, nurses, and outreach workers engage in simulated conversations with diverse virtual patients tailored to real HIV care challenges.
- Analyze: The system uses Al to evaluate both verbal (text) and nonverbal (speech) cues, drawing on insights from 100+ annotated real clinic visits (from the UNBIASED dataset, <a href="https://www.unbiased.health">https://www.unbiased.health</a>).



3. **Reflect**: Users receive personalized, digestible feedback on their social signals—such as engagement, warmth, and dominance—and how these may impact care.

### Who It's For

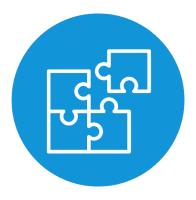
- · HIV providers, counselors, and researchers
- Community health workers and outreach teams
- Anyone working with PLWH and high-risk populations

Whether at the front desk or in clinical care, ConversHIVe supports inclusive communication practices that improve patient trust and health outcomes.

### **Our Vision**

By empowering care teams with actionable feedback and low-barrier training, ConversHIVe aims to improve healthcare delivery for underserved populations—and ultimately help end the HIV epidemic in California and beyond.

### Clinical, Social, Behavioral, and Implementation Sciences



Portfolio: Strengthening California's Support Systems for Persons Living with HIV 2025 to 2029

PI: Janet Myers – UCSF











# Project Title: The California Reentry Capacity Collaborative Building Capacity to Implement and Evaluate HIV Programs for Justice-Involved People in California

**Background:** Improving continuity of care and maintenance of virologic suppression (VS) among justice-involved people with HIV (JI-PWH) is critical to ending the HIV epidemic and curtailing future pandemics. Medical care that is available during incarceration is often not accessible to JI-PWH after they have been released. Consequently, for people with HIV, health status indicators often decline following release from incarceration, which increases individual poor health outcomes and risk of forward transmission of HIV in the community. For these reasons, ensuring continuity of care for this vulnerable population is a public health priority with farreaching consequences for HIV and other infectious diseases.

**Project Aims:** Funded by the State Office of AIDS, this project aims to conduct capacity building among JI-PWH serving and potentially serving provider organizations working with local jails and serving people returning from all settings of incarceration to local communities. In this one-year project (with the potential for follow-on years), we will:

<u>Aim 1:</u> Conduct a situational assessment of how counties are implementing existing services for people with HIV returning to the community from carceral settings, including:

The ADAP Jail Pilot Program that reimburses the cost of medications for jails certified by the OA

The CalAIM Enhanced Care Management program (ECM) that makes funds available for complex care (including for justice-involved clients)

<u>Aim 2:</u> Support capacity building among JI-PWH serving and potentially serving provider organizations, we are convening a <u>Reentry Practice Collaborative (RPC)</u> comprised of:

- Providers working in carceral settings (primarily jails)
- Providers working in JI-PWH-serving community-based organizations
- Subject matter experts



### **Project Team:**

Janet Myers, PhD, MPH (PI)
Graham Hinchcliffe, MS (Project Director)
Kim Koester, PhD (Co-I)
Katie Kramer, PhD (Subject Matter Expert and Collaborative Lead)

Orlando Harris, PhD (Co-I)
Lissa Moran, MPH (Qualitative Analyst)
Ben Zovod (Project Coordinator)
Jennifer Bie (Unit Manager)

### Progress and next steps:

- Survey of ADAP Pilot sites completed.
- Survey of CalAIM justice-involved providers is underway.
- The first meeting of the Reentry Practice Collaborative is planned for November.



### **Policy Research**



Portfolio: Policy Research Centers
2025 to 2027

Co-PI: Emily Arnold – UCSF, Laura Thomas – SFAF, and Stefano Bertozzi – UCB

Co-PI: Ian Holloway – UCLA and Jamila Stockman – UCSD

Co-PI: Laramie Smith – UCSD and Orlando Harris – UCSF



### **Northern California HIV Policy Research Center**

Our Team is a collaboration between UCSF, UC Berkeley, and the San Francisco AIDS Foundation. We also rely on the Organizing Committee of the Ending the Epidemics Coalition, and Ryan Clary in particular.

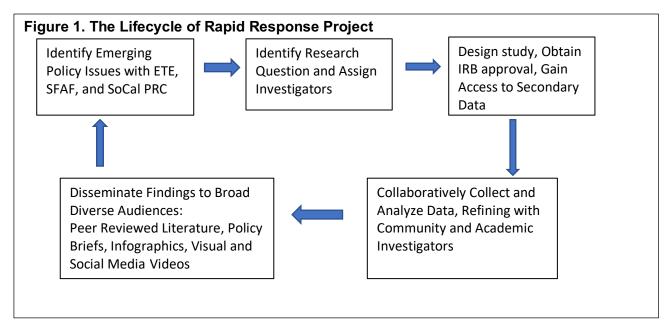
UCSF: Emily Arnold, Kim Koester, Lissa Moran, Simon Outram, Wayne Steward

UC Berkeley: Stefano Bertozzi, Lauren Hunter

San Francisco AIDS Foundation: Laura Thomas, Ernest Hopkins

The overall goal of the Northern California HIV/AIDS Policy Research Center is to provide timely and relevant data-driven research to inform the health care system and policy arena related to HIV, Hepatitis C, STIs, and harm reduction in California. Relying on an academic (UCSF and UC Berkeley) and community partnership (San Francisco AIDS Foundation), and the Ending the Epidemics (ETE) coalition, we use a rapid response cycle to elicit research topics, design and implement studies, and disseminate our findings.

Our team intentionally uses an iterative and collaborative model to develop, carry out, and share timely policy-related rapid response studies, the rapid response cycle.



In our recent cycle, our involvement and regular presence at ETE coalition meetings have allowed us to effectively identify emerging and timely HIV-related policy issues, leading to ongoing rapid response research in 4 areas:

- 1) Maintaining HIV care and treatment for re-entry populations: Understanding the barriers to and facilitators of re-engagement in care after incarceration is essential to ensure equitable access to ART and achieve state and national goals for HIV control. In collaboration with the California Department of Public Health Office of AIDS (CDPH OA), the California Correctional Health Care Services (CCHCS), and the California Department of Corrections and Rehabilitation (CDCR), we are documenting recent trends in continuity of care among people living with HIV before and after release from prison.
- 2) **Retaining the HIV workforce**: Workforce retention has become a significant challenge, particularly in the wake of the COVID pandemic. We recently launched a rapid response to document best practices for retaining the HIV workforce, and are in the process of conducting a systematic review of the literature on this topic. Our team has been conducting interviews with staff and executives in community- and clinic-based settings providing HIV prevention and care services to key populations impacted by HIV.
- 3) Syndemic frameworks and addressing HIV and its co-morbidities. It is well established that social factors such as education, employment, income, housing status, and racial identity are causally related to a wide variety of health outcomes, including HIV. Epidemiological data suggests a similar causal relationship, with social determinants of health (SDOH) being strongly related to incidence of HIV and retention in care/treatment. There have been two recent legislative efforts in California to make it mandatory for Medi-Cal patients to be screened for SDOH as standard practice, both of which were unsuccessful. The study would enhance our understanding how syndemic theory and/or the framework for understanding SDOH might be put into practice, yielding insights into better programming to improve the overall health of individuals living with HIV.
- 4) Changes to the 340B reimbursement structure on revenue streams for HIV-related services, and implications for these on clinic-based services for HIV-impacted communities. ETE Coalition members, as well as our community partners affiliated with the San Francisco AIDS Foundation, AIDS Project Los Angeles, and the LA Gay and Lesbian Center all raised the issue of changes to 340b drug pricing and the potential impact that cuts could make to community-based programs serving communities effected by HIV. Policy passed at the federal level as part of the Inflation Reduction Act cut 340b reimbursements and will substantively reduce this important revenue stream, threatening the continuation of supported HIV services. Our team completed a rapid response to model the potential extent of a 340b revenue loss and to examine how such cuts would likely translate into a loss or reduction in services, focusing on the development of funding simulations that estimate the amount of revenue being generated by the 340b for providers of HIV services, and then estimating the amount of funding that would be lost to California entities based on various proposals to reform the 340b program, which we shared in a policy brief, as well as a toolkit.

### Southern California HIV/AIDS Policy Research Center

For over 15 years, the Southern California HIV/AIDS Policy Research Center (SCHPRC) has led a multidisciplinary team of community leaders, scientific experts, and dedicated staff, bringing the most relevant and timely evidence to bear on HIV policymaking in California



Photo: ETE Convening 2022

### **Partners and Team Members:**

- University of California, Los Angeles (UCLA): Ian Holloway, Ayako Miyashita Ochoa, Nina Harawa
- University of California, San Diego (UCSD): Jamila Stockman
- University of California, Riverside (UCR): Brandon Brown
- APLA Health: Phil Curtis, Katja Nelson, Sebastián Perez
- TruEvolution: Ariel Savage



### Aims:

- (1) Identify emerging policy issues related to HIV and related syndemics through engaging key stakeholders, including consumers, healthcare and social service providers, advocates, and policy makers;
- (2) Conduct objective, rigorous rapid response research to address such issues, including topics related to HIV disparities, viral hepatitis, sexually transmitted infections, and overdose; and
- (3) Inform policy making by disseminating relevant and timely research findings.

### **Key Outcomes:**

- Convene annual meeting with SCHPRC partners and stakeholders to discuss emerging HIV policy issues, prioritize rapid response research and SCHPRC activities for the program year
- Continuously support, implement, and participate in Ending the Epidemics Strategic Planning process
- Execute rapid response research
- Disseminate research findings
- Review proposed legislation and update CHPRC Legislation Tracker continuously

### **Project Progress Highlights:**

- Pharmacist-based HIV prevention:
  - Brief Report: <u>Law and Policy Interventions Addressing Pharmacy Benefit Manager (PBM)</u>
     <u>Practices: Impact on Pharmacy-based HIV Prevention Services</u>
  - Brief Report: <u>Pharmacist-delivered PrEP and PEP in California</u>: <u>Changes under Senate Bill</u>
     339 in 2024
- Doxy-PEP:
  - o Policy Brief: <u>Doxy-PEP: What Do We Know?</u>
  - o Infographic: coming soon
- Mpox:
  - o Brief Report: Mpox Vaccination in California: Results from a Community Survey
  - o Infographic: Already Vaxxed for Mpox Community Survey
- <u>Legislation Tracker</u>: Tracking 15 bills and policies that impact people living with or at-risk for HIV/AIDS in California (Legislative year 2025-2026)

**Next Year:** Continue to conduct rapid response research, track relevant legislation, and convene stakeholder meetings, and disseminate research findings to impact California law and policy.

**Challenges:** The current political environment has presented significant challenges for researchers and community partners. Federal policy changes and funding instability has impacted staffing, project continuity, and the ability to prioritize rapid response research initiatives.



### We at the California Center for HIV Syndemic (CalCenSyn) Policy Research are pleased to meet you!



Community Partners: Aaron Armer (Sacramento LGBT Center), Maurice Tobin (Oakland LGBTQ Center) Tara Stamos-Buesig (Harm Reduction Coalition of San Diego), CJ Tobe (DAP Health); Academic Partners: Drs. Jamila Stockman, Tommi Gaines, Natasha Martin, Nicole Kelly, Maryam Hussain (UCSD)



Leadership: Drs. Laramie Smith (UCSD), Orlando Harris (UCSF); Coordinators: Martín Ibarra (UCSD), Myiesha Phelps (UCSD), Jük Egbunike (UCSF)

#### Who are we?

CalCenSyn is a policy research center. We focus on the social and structural issues that link HIV to other (syndemic) health inequities in California (e.g., violence, immigration, housing, and substance use). We are funded\* to lead this collaborative work with communities often overlooked in California's HIV response.

CalCenSyn leadership, coordinators, community and academic partners are personally connected to the needs and impact we want our policy work to have in our communities.

### How can we support your organization's important work?

California has led advances in HIV treatment and prevention and policy efforts to End the HIV Epidemic (EHE). Still, multiple marginalized and underserved groups, including sexual and gender minorities, Black, Brown, Indigenous, and low-income communities, are often left behind.

Our goal is to partner with frontline organizations committed to serving these communities. This way, we can work together to inform policies addressing the social and structural issues that matter to you. Through our partnership, we aim to lead local and statewide change in HIV and other syndemic health-related policy, research, and practice.

### What will we do?

In the coming years (Jan. 2025 – Jan. 2027), we aim to build community partnerships and co-lead policy projects that address the needs of organizations across Sacramento, Alameda, Riverside, San Bernardino, and San Diego Counties. We are prioritizing counties that remain underrepresented in California's EHE response.

Our community-academic collaborative (CAC) policy research involves frontline organizations from start to finish:

- 1. Our CAC leads three policy work in progress meetings a year with local organizations in our EHE counties to ensure community voices and syndemic-related needs are prioritized in our Center's work.
- 2. Our CAC members use these priorities to co-develop, lead, and disseminate rapid policy research projects to address the syndemic drivers of HIV inequities in our EHE counties.
- 3. Our CAC partners with local organizations to share research findings and identify solutions to ending the HIV epidemic in California communities with the highest burden of HIV diagnoses and related disparities.

### How do we hope to change the HIV syndemic-related policy outcomes locally and statewide?



Ending the HIV epidemic requires a bold, comprehensive, innovative approach that is community-engaged and scientifically driven. Our mission is to expose the root causes of HIV and syndemic conditions and serve as a leading community-focused policy center that pushes boundaries in HIV policy, research, and practice to achieve health equity in all California communities.

Contact Us: CalCenSynPolicy@health.ucsd.edu – www.chprc.org