Updates on Biomedical Prevention at City Clinic

Montica Levy, MPH
Biomedical Prevention Coordinator
Disease Prevention and Control Branch
SFDPH



Disclosures

 The views expressed herein do not necessarily reflect the official policies of the City and County of San Francisco; nor does mention of the San Francisco Department of Public Health imply its endorsement.

Acknowledgements

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Alejandro Vigil Biomedical Prevention Navigator



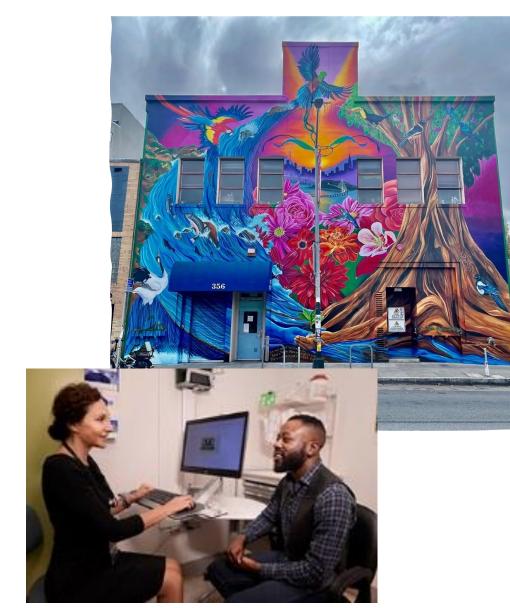
Grecia Sambrano Public Service Aide



SF City Clinic is Our Hub for Sexual Health Services,

Training and Research

- High Volume: 13,000 visits annually
- Serve a diverse population
 - 28% Latinx, 15% B/AA, 13% Asian, 31% White
 - 40% <30 years
 - 50% LGBTQ
- Integrated services:
 - STI, HIV, HCV screening, diagnosis and treatment
 - Partner services and counseling (home to LINCS)
 - Women's health
 - Behavioral health
 - Pre- and Post-exposure prophylaxis (PrEP and PEP)
 - Doxy-PEP
 - On site laboratory
 - Immunizations (including COVID-19)
 - Overdose prevention (Narcan and fentanyl test strips)



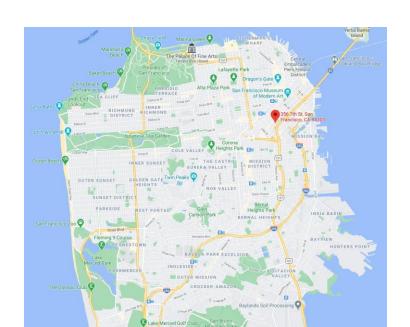
SF City Clinic plays an important role in landscape of sexual health services in SF and the Bay Area

- Citywide, diagnosis site for 8% of chlamydia, 12% of gonorrhea and 15% of syphilis cases
- Diagnose approximately 40 people/year with HIV
- Provide RAPID ART initiation or re-initiation to >100 patients/year
- Initiate 200-225 people/quarter on PrEP; >5000 since 2013 (55% uninsured or on Medi-Cal); about 900 on PrEP at any given time
- Initiated 828 people on doxy-PEP since launch in November 2022
- During mpox outbreak:
 - Diagnosed 14% of cases
 - Largest provider of tecovirimat (185 patients treated)
 - Equitable access to vaccine (38% of people vaccinated at SFCC were Black or Latino; citywide 24%)

How we provide patient-centered clinical care

Clinic structure

- Location
- Onsite lab
- No billing, work with almost any insurance (not Kaiser or Veterans Administration)



Staffing

 Diverse staffing in terms of race, language, gender, and sexual orientation

PrEP program

- All staff clinicians can Rx PrEP
- Highly skilled PrEP navigators with broad scope:
 - Expert benefits navigation
 - Comprehensive protocolized express PrEP follow up visits for asymptomatic pts under standing order protocol
 - Panel mgmt. and other coordination duties that do not require clinical licensure

How we provide patient-centered clinical care

Visit models

- Allow drop-in
- Always work to reduce wait times during visit
- Same-day GC/CT diagnosis for asymptomatic patients, using Cepheid GeneXpert



• For PrEP:

- Same-day PrEP starts at first visit
- Comprehensive protocolized express PrEP follow up visits for asymptomatic pts under standing order protocol
- Allow 1-month Rx extensions by phone
- Combined PrEP/PEP start, all one visit with 3month Rx
- Handing out pills when needed

PS 20-2010 Comp C Accomplishments:

- Customized Epic to support PrEP at SFCC and throughout SFHN
 - Built PrEP registry -> critical for panel management and program evaluation
 - Structured data on strategy (daily, 2-1-1, LAI) and adherence
 - Developed smartsets, smartphrases and PrEP synopsis
- Launched express services
 - Navigator-led PrEP express
 - Nurse-led asymptomatic screening visits
- HIV VL monitoring in PLWH to identify people NIC
- Clinic mural

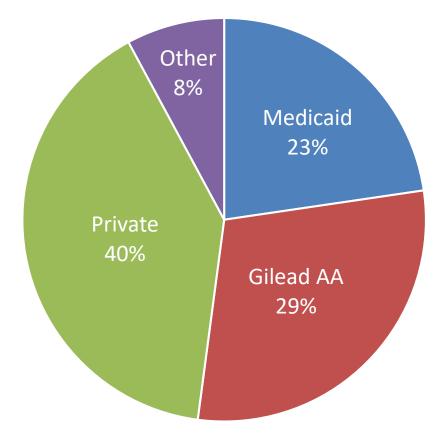




City Clinic PrEP Program

- >5000 PrEP starts since 2013, ~900 currently enrolled
- PrEP Demonstration Project started 2012, then launched permanent program 2014
- Our team generates PrEP demand mostly via our website, word of mouth, and referrals from other inclinic services

Program demographics by coverage type



Injectable PrEP implementation in SF

- Estimated 200 people using CAB between City Clinic, Magnet, Ward 86, and Kaiser SF, more data forthcoming via GTZ surveillance project
- Barriers for privately insured patients
- Buy and bill vs. white bagging
 - City Clinic uses white-bagging, so same day start not possible (takes 1-3 weeks from screening visit to 1st injection)

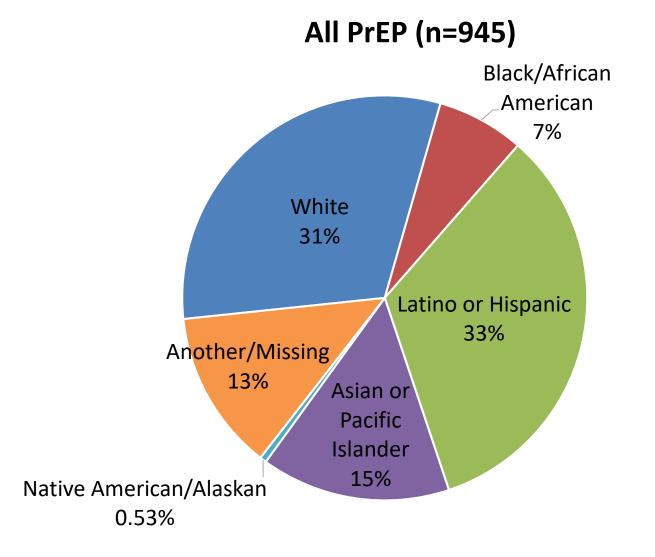
Injectable PrEP implementation at City Clinic

- 39 patients have had 1st injection as of 6/30/23
- 33% had not gotten oral PrEP from City Clinic prior to CAB
- Medi-Cal and uninsured only
- Time-intensive, so only enrolling patients with a current or anticipated clinical need, e.g. challenges taking a pill (including PEH/staying in shelter), renal insufficiency, etc.

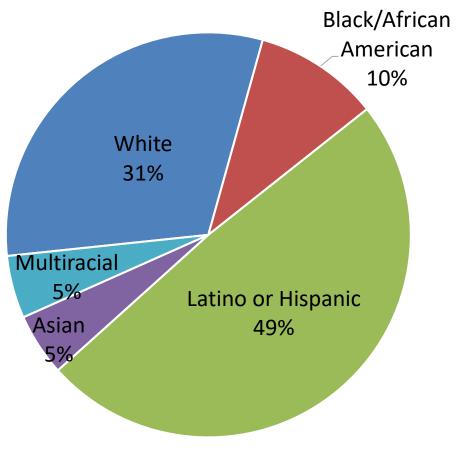
City Clinic PrEP Program Demographics by Gender

	All PrEP	Injectable PrEP
	n=945	n=39
Cis men	91%	74%
Cis women	2%	8%
Trans men	0.32%	3%
Trans women	3.17%	10%
Another gender/Missing	3.28%	5%

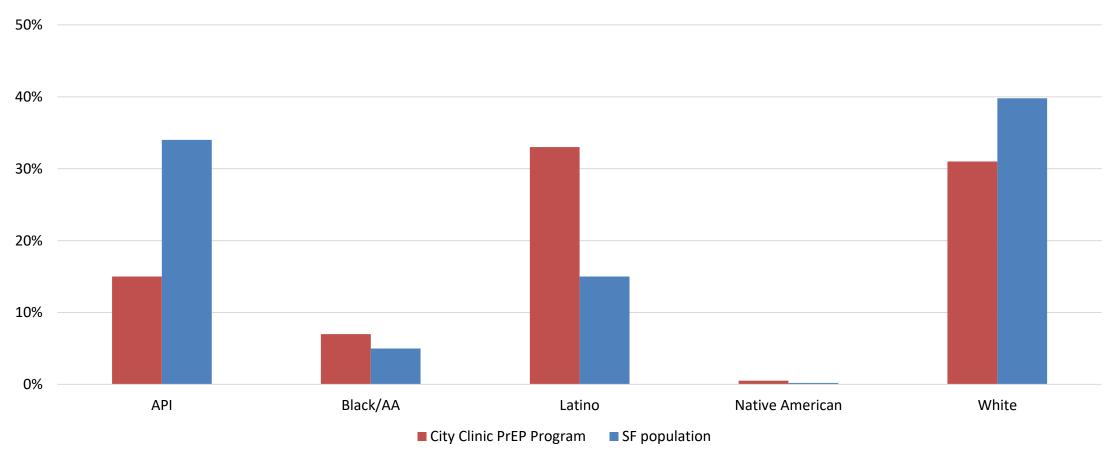
City Clinic PrEP Program Demographics by Race



Injectable PrEP (n=39)



Racial Demographics in City Clinic PrEP Program vs SF Population



Doxy-PEP Implementation in US

- CDC STI Treatment Guidelines do not include a recommendation for or against Doxy PEP
- Participants rolling-off of the doxy-PEP study requesting doxy-PEP from their PCPs
- Some clinicians prescribing, mostly on a case-by-case basis
- Community interest high

Note added to CDC STI Treatment Guidelines in July 2022

Doxy-PEP as an STI Prevention Strategy: Considerations for Individuals and Healthcare Providers of Gay or Bisexual Men or Transgender Women

As CDC and others work quickly to <u>evaluate data</u> to inform clinical guidance on the safe and effective use of doxycycline post-exposure prophylaxis (doxy-PEP) to prevent gonorrhea, chlamydia, and syphilis, we acknowledge there are individuals and clinicians who are already engaged in the off-label use of doxycycline as bacterial STI post-exposure prophylaxis or considering it. As such, we are providing the following considerations to inform those decisions:

- <u>Current efficacy data</u> only applies to gay and bisexual men and transgender women. Studies among heterosexual cis-gender women are ongoing.
- Doxycycline 200 mg administered within 24-72 hours of condomless sex was the regimen evaluated in this study. Other antibiotics should not be considered for PEP.
- In addition to informing patients about the potential STI prevention benefits of doxy-PEP, providers should also counsel patients about potential adverse side effects of doxycycline including phototoxicity, gastrointestinal symptoms, and more rarely esophageal ulceration.
- Providers should continue to screen, test, and treat for bacterial STIs in accordance with <u>CDC's STI Treatment</u> <u>Guidelines</u> and <u>CDC's PrEP for the Prevention of HIV guidelines</u> , even among people who may be using doxycycline as PEP or PrEP.

Snapshot from: https://www.cdc.gov/std/treatment-guidelines/clinical-primary.htm#CautionsForDoxyPEP

SFDPH Released Interim Guidelines for Doxy-PEP





Health Update

Doxycycline Post-Exposure Prophylaxis Reduces Incidence of Sexually Transmitted Infections

October 21, 2022

Situational Update

Researchers at the San Francisco Department of Health (SFDPH), Zuckerberg San Francisco General, University of California, San Francisco, and the University of Washington recently collaborated on a randomized controlled clinical trial of post-exposure prophylaxis (PEP) of sexually transmitted infections (STIs) using a single dose of doxycycline 200 mg within 72 hours after oral, anal, or vaginal sex, in men who have sex with men (MSM) and transgender women (TGW) who were living with HIV (PLWH) or taking HIV pre-exposure prophylaxis (HIV PrEP). The study showed that this regimen significantly reduced acquisition of chlamydia, gonorrhea, and syphilis in these populations.

Participants randomized to doxycycline PEP (doxy-PEP) had a 66% (HIV-negative and on PrEP) and 62% (PLWH) reduction in STIs per quarter of study follow-up, compared with participants randomized to standard of care (no doxy-PEP). Taking doxycycline was also safe and well-tolerated by participants, with no drug-related serious adverse events. These data were recently presented at the 2022 International AIDS Conference in Montreal, Canada. Data are still being collected and analyzed to assess the impact of doxy-PEP on risk for drug resistance in bacterial STIs, *Staph aureus*, and commensal *Neisseria*, and on the gut microbiome.

The CDC has released <u>considerations</u> for doxy-PEP as an STI prevention strategy, but there is not yet detailed guidance from CDC on doxy-PEP, for which its indication is currently off-label. STIs can cause significant morbidity and reducing STI rates in San Francisco is an urgent public health priority. **Doxy-PEP** is the first biomedical prevention tool that has been shown to be effective and well-tolerated, community awareness is growing, and many providers in SF are already prescribing doxy-PEP to their patients at risk for STIs. SFDPH is providing guidance to SF clinicians on the use of doxy-PEP to reduce STI incidence in MSM and TGW at risk of bacterial STIs.

SFDPH Doxy-PEP Interim Guidelines

- 1. Recommend doxy-PEP to cis men and trans women who: 1) have had a bacterial STI in the past year and 2) report condomless anal or oral sexual contact with ≥ 1 cis male or trans female partner in the past year. These were the eligibility criteria used for the DoxyPEP study. Patients with a history of syphilis should be prioritized for doxy-PEP.
- 2. Offer doxy-PEP using shared decision making to cis men, trans men and trans women who report having multiple cis male or trans female sex partners in the prior year, even if they have not previously been diagnosed with an STI.

3. Doxy-PEP not recommended for cis women based on currently available evidence from Kenya DPEP study.

CDPH Released Interim Guidelines for Doxy-PEP



State of California—Health and Human Services Agency California Department of Public Health



GAVIN NEWSOI Governor

April 28, 2023

Doxycycline Post-Exposure Prophylaxis (doxy-PEP) for the Prevention of Bacterial Sexually Transmitted Infections (STIs)

Dear Colleague,

The California Department of Public Health (CDPH) would like to inform all health care providers of a compelling new biomedical intervention to prevent bacterial STIs. Emerging evidence from a study among men who have sex with men (MSM) and transgender women (TGW) suggests doxycycline, when taken as doxy-PEP after condomless oral, anal, or vaginal sex, significantly reduces acquisition of chlamydia (CT), gonorrhea (GC), and syphilis. Given the high rates of these STIs in California², CDPH recommends the following:

- Recommend doxy-PEP to men who have sex with men (MSM) or transgender women (TGW) who have had ≥1 bacterial STI in the past 12 months.
- Offer doxy-PEP using shared decision-making to all non-pregnant individuals at increased risk for bacterial STIs and to those requesting doxy-PEP, even if these individuals have not been previously diagnosed with an STI or have not disclosed their risk status.ⁱ
- Provide comprehensive preventative sexual health counseling and education to all sexually-active individuals to include HIV/STI screening, doxy-PEP, HIV pre-exposure prophylaxis (<u>Prep</u>)/HIV post-exposure prophylaxis (<u>PEP</u>), <u>vaccinations</u> (e.g. Hepatitis A/B, <u>Human Papilloma Virus</u>, <u>Mpox</u>, <u>Meningococcal/MenACWY</u>), <u>expedited partner therapy</u>, and/or <u>contraception</u> where warranted.

City Clinic doxy-PEP program overview

- Integrated into existing PrEP program
- Open to pts with any insurance but Kaiser or VA
- "Status neutral" Open to pts living with HIV or not
- All patients see a clinician at doxy-PEP initiation
- Doxy e-prescribed for patients with insurance
- Doxy dispensed in clinic (no cost to patient) for uninsured and <500% FPL
- Dispense 60-100 pills (30-50 doses)
- Annual LFTs

- Biomedical HIV prevention team (PrEP navigators) provide critical support to the program
 - Determine patients' coverage (eRx vs. dispense in clinic) and "pend" the prescription
 - Provide education, information and counseling
 - At follow-up visits, collect information on sexual practices and doxy-PEP use



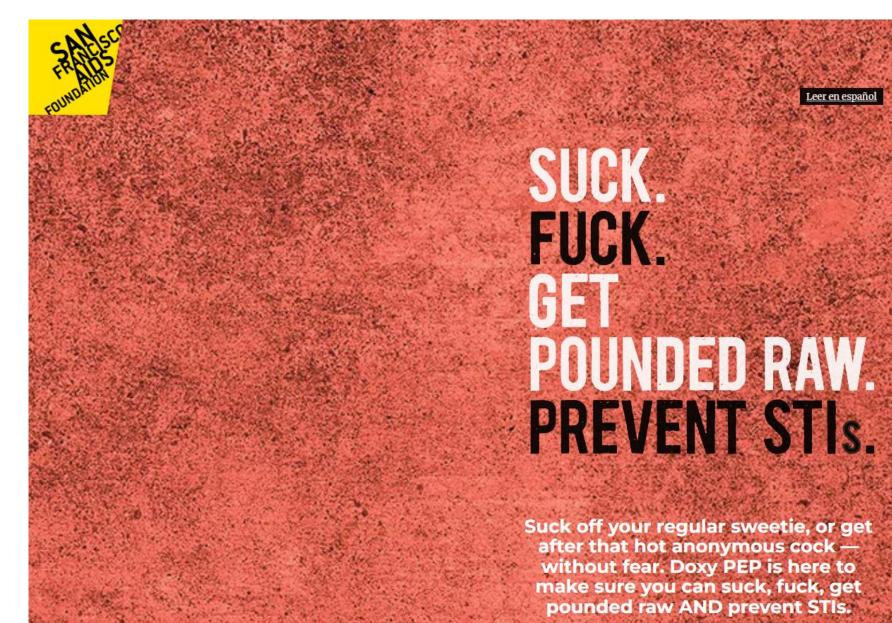
Doxy-PEP at City Clinic: High uptake by persons who would benefit from it

- 828 patients started doxy-PEP at SFCC 11/3/22 6/6/23
- Vast majority are in our PrEP program
- Seeing patients whose PrEP/ART provider does not Rx doxy-PEP
- Racial and gender demographics closely mirror our PrEP program

Early insights from doxy-PEP at City Clinic

- Confusion about dosing and how it differs from 2-1-1 PrEP or daily PrEP
- Most do not need refills at first quarterly continuation visit
- Anecdotal reports from patients of using it selectively: with new or "random" partners, rather than trusted partners

Doxy-PEP in the community



THANK YOU!

- More info: sfcityclinic.org
- To access PrEP, PEP, or doxy-PEP at City Clinic, please call 628-217-6692