

# Lessons Learned from the US PrEP Demonstration Project: Moving from the “real world” to the “real, real world”

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# 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.
- Gilead Sciences provided study drug for the PrEP demo project.

# Outline

- The Demo Project
  - Uptake
  - Adherence
  - Risk behaviors
  - STI/HIV incidence
- Next steps for PrEP implementation
  - Post-study access
  - PrEP navigation at SF City Clinic



# The Demo Project

San Francisco  
demonstration  
project



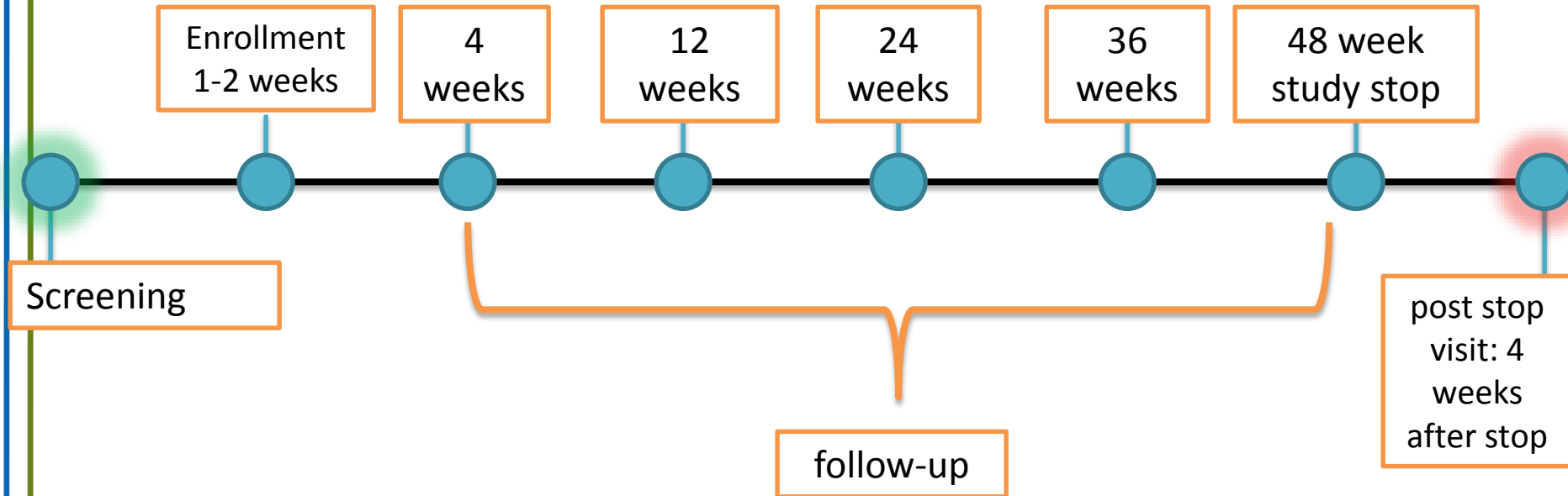
- NIAID-funded, multisite, open-label PrEP Demonstration Project
- Conducted at 2 STD clinics and a community health center from Sept 2012- Feb 2015
- Key objectives:
  - PrEP uptake
  - Adherence / Retention
  - Sexual behaviors and STIs
  - Side effects and toxicities
  - Resistance in seroconverters
  - Determine staff and space needed for PrEP delivery

## ELIGIBILITY

- MSM or TG woman
- HIV negative
- At risk for HIV-infection:
  - Condomless anal sex  $\geq$  2 partner
  - $\geq$  2 episodes of anal sex w/ HIV+ partner
  - Syphilis, Rectal GC or CT
- Age  $\geq$ 18
- Fluent in English or Spanish
- Normal renal function
- Hepatitis B negative
- No medical contraindications

Last 12  
mo.

# Methods: Follow-up and monitoring



## MONITORING:

- HIV testing: Rapid HIV Ab and 4<sup>th</sup> gen HIV Ag/Ab assay at ALL visits; *plus* HIV RNA (Individual or Pooled) at enrollment
- Kidney function: Creatinine and urine protein (dipstick): Screening and q3mo
- Hepatitis B: HBsAg at screening
- STDs: Syphilis; Urethral, rectal and pharyngeal GC/CT – Screening and q3mo

# Integrated Counseling: Risk Reduction and Adherence counseling

## Risk reduction

- Sexual and drug using behaviors and current efforts for remaining HIV negative
- How PrEP fits in with overall sexual health goals/plan

## Adherence

- PrEP basics handout (at PrEP initiation)
- Discuss pill-taking experience
- Facilitators/barriers
- Strategies

## PrEP Basics

### 1. Medication Instructions

- There are 30-pills of Truvada in each bottle (30-days worth of PrEP).
- Please bring back any leftover pills (in the original bottles, with study label) to each visit.
- Store the bottle at room temperature (not in fridge/hot car).

### 2. One Pill Per Day

- Take 1 pill every day.
- Only daily PrEP has been shown to be effective
- People who use PrEP more consistently have higher levels of protection against HIV.
- We have no evidence that taking more than one pill a day gives any additional protection. In fact, taking too many can be bad for your health or make you feel sick.
- There are studies going on right now to try to see if less than once a day PrEP would still help to protect people from HIV, but there are no results from these studies yet. Based on what we know right now, we recommend people to take PrEP as close to daily as possible.
- This medication can be taken with or without food.
- This medication can be taken when drinking alcohol or using drugs.

### 3. Potential Side-effects and “Start-up” Syndrome

- Some people experience a “start-up” syndrome when beginning Truvada for PrEP. This may involve gas, bloating, softer/more frequent stools, or nausea.
- These symptoms are usually mild and go away after the 1st month on PrEP.
- Strategies to deal with stomach related symptoms:
  - take pill with food/snack
  - take pill at night before bedtime
- Contact study staff if you have side effects. We can help.

### 4. Sometimes Doses Are Missed

- People sometimes forget or skip doses. It is not uncommon.

- PrEP is likely to be effective even when occasional doses are missed.
- If you forget a dose just take it when you remember. For example:
  - *If usually take in AM, but realize at 10 pm that you forgot, it’s ok to take 1 pill then and continue with your usual schedule the next day.*
  - *If the next AM you realize you missed your pill yesterday, just take 1 pill then and continue with your usual schedule the next day.*
- Avoid “double dosing” – Do NOT take two pills at one time because you forgot to take one the day before. Just get back on track with one pill a day.

### 5. Getting into a Routine

- Many people find it helpful to take their pills at the same time as something else they regularly do each day (e.g. eating breakfast, brushing teeth).
- Reminders (alarms or seeing the bottle somewhere you look each day) can also help.
- Pill boxes are available for you if you want to try one.
- When routines are disrupted (e.g., staying out overnight, going on vacation, skipping meals), consider carrying extra pills on you (e.g. keychain, wallet, tin foil).

### 6. Stopping PrEP

- Whether or not you want to take PrEP for the full 12-months is your decision.
- If you choose to stop PrEP, please call us and let us know. You do NOT need to be taking PrEP to remain in the study.

### 7. Restarting PrEP

- If you have stopped PrEP for more than 7 days and would like to re-start, please call us and let us know so that we can help you do this safely.
- Getting an HIV test before you re-start PrEP is very important. If you are already infected with HIV and take Truvada, the virus could become resistant to this medication which means that the medication will no longer work for HIV treatment.

### Questions/Concerns

- Call ###-###-#### if you have any questions or concerns.
- If you have an emergency, call 911 or go to the hospital emergency room.



# PrEP eligibility and uptake

Uptake cascade	Total
Approached for pre-screening	1069
Declined	364
Ineligible	148
Enrolled	557
Uptake among potentially eligible	<b>60%</b>

## Significant demand for PrEP, amplified by word of mouth

- Waitlists in SF and DC
- Number of “self-referrals” increased during enrollment period
- 65% of self-referred pts had learned about PrEP from a friend or sex partner

## Main reasons for joining the study

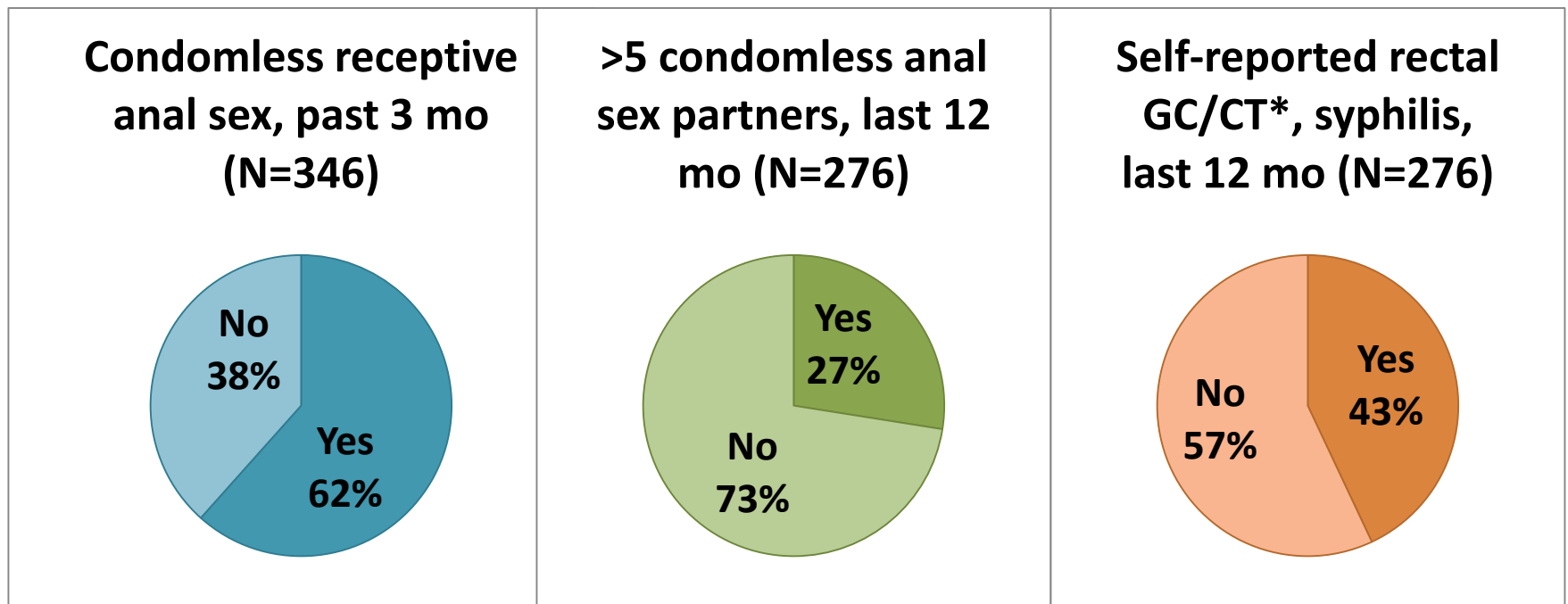
- To protect myself against HIV
- To help the community/to help fight the HIV epidemic
- Because my partner has HIV
- To make it safer for me to have sex without condoms

## Main reasons for declining

- Not enough time for study participation
- Concerns about side effects
- Not perceiving oneself as at risk for HIV
- Wants more time to think about it

# Substantial proportion declining PrEP were at risk for HIV acquisition

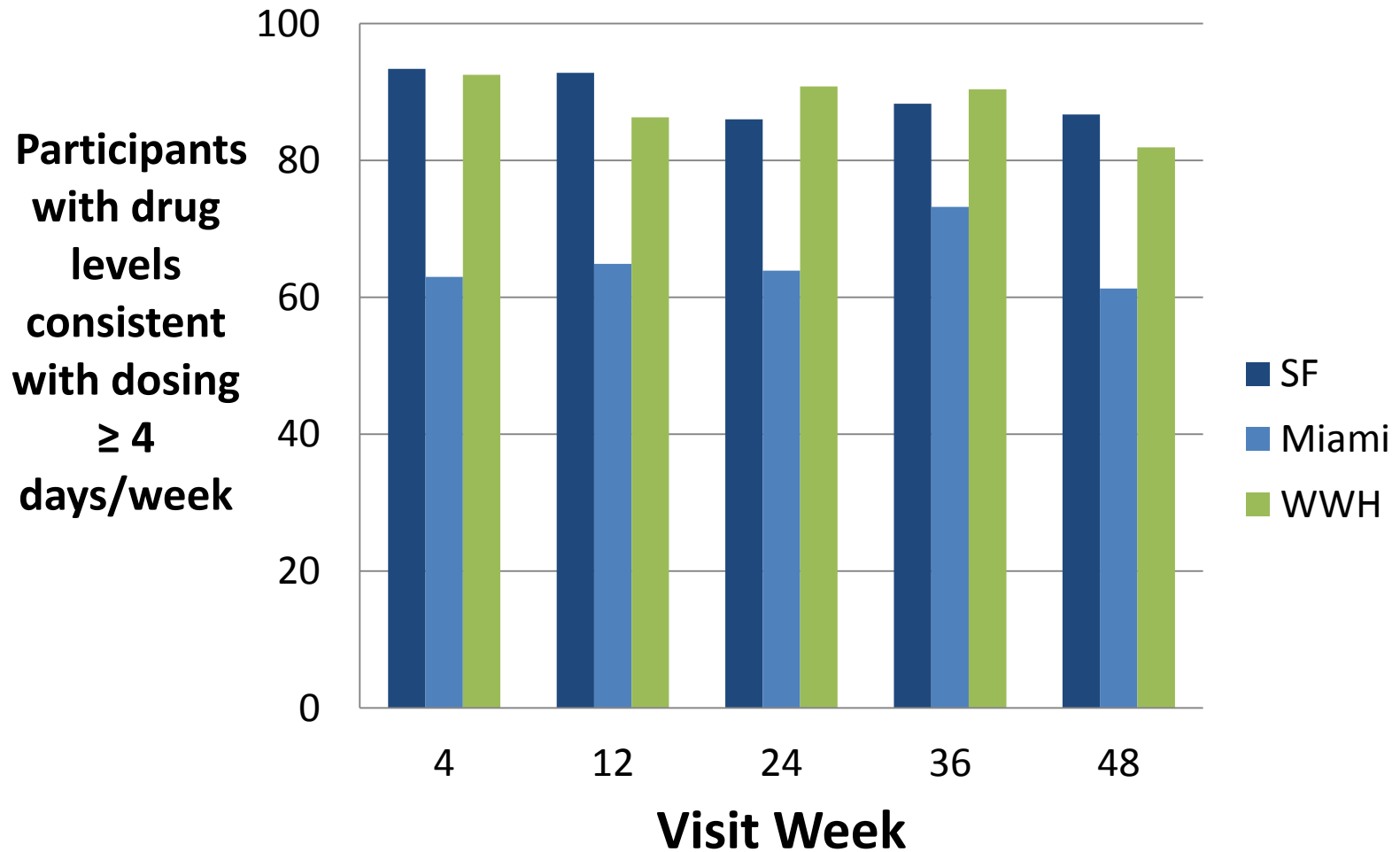
- Among participants who declined participation and provided sexual behavior data:



\*Gonorrhea, chlamydia



# Adherence to PrEP



# Do Risk Behaviors Change on PrEP?

Behavior (past 3 months)	Screening	48 weeks	Trend
# Anal sex partners	10.9	9.3	↓
# Receptive anal sex episodes	14.9	11.4	↓
# Receptive anal sex episodes without a condom	8.9	8.9	No Change
# Receptive anal sex episodes with a condom	6.0	2.5	↓
% Reporting any condomless RAS	65.5%	65.6%	No Change

# Sexually Transmitted Infections and PrEP

- 26.4% of participants had GC, CT or early syphilis at baseline
- 50.9% had at least one STI during follow-up
- STI incidence was high but did not increase over time

Infection	# Infected at baseline (%)	Re-infected during follow-up; N (%)
Rectal GC or CT	95 (17.1)	44 (59.7)
Urethral GC or CT	40 (7.2)	7 (21.2)
Pharyngeal GC or CT	69 (12.4)	15 (25)
Early syphilis	24 (4.3)	2 (9.1)

# HIV Infections

- 3 participants had acute HIV infection at enrollment (all were 4<sup>th</sup> generation HIV Ag/Ab negative)
- 2 seroconversions
  - 1<sup>st</sup> ppt reported last taking PrEP 37 days prior to seroconversion and had DBS levels <2 doses/week at his seroconversion and all prior visits
  - 2<sup>nd</sup> ppt seroconverted 4 weeks after the 48 week visit and had DBS levels consistent with daily dosing at week 4, which dropped to <2 doses/week through week 24, and were undetectable thereafter
- HIV incidence 0.43/100 PYs (95% CI 0.05-1.54)

# Access to PrEP in the “real, real world”

Follow-up survey administered to all Demo participants 4-6 months after completing the study

	SF N=74	Miami N=100	Total N=174
Interested in taking PrEP post study	65 (87.8)	83 (83)	148 (85)
Discussed PrEP with a provider	58 (78.4)	31 (31)	89 (51.1)
Have taken PrEP post study	51 (68.9)	23 (23)	74 (42.5)

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# Demo Project: Lessons Learned

- High demand for PrEP
  - Very good retention and adherence, but with variation by race/ethnicity, site, and sexual risk
  - Low HIV incidence, high STI incidence
  - Feasible to deliver in an STD clinic setting
  - High levels of interest in continuing PrEP -- addressing PrEP access issues is critical
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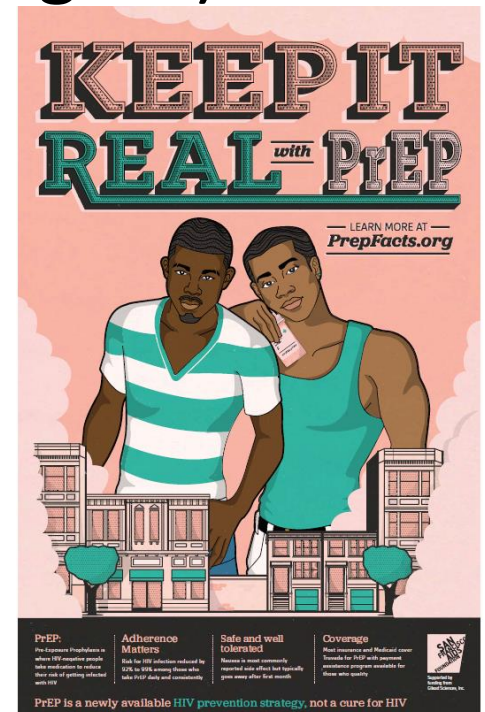
# Supporting PrEP uptake in SF

- Increase PrEP knowledge and demand among those at risk for HIV-infection
- Build capacity among providers to prescribe PrEP
- Combat PrEP related stigma among friends, sex partners and medical providers
- Develop tools to support PrEP users
- Improve affordability



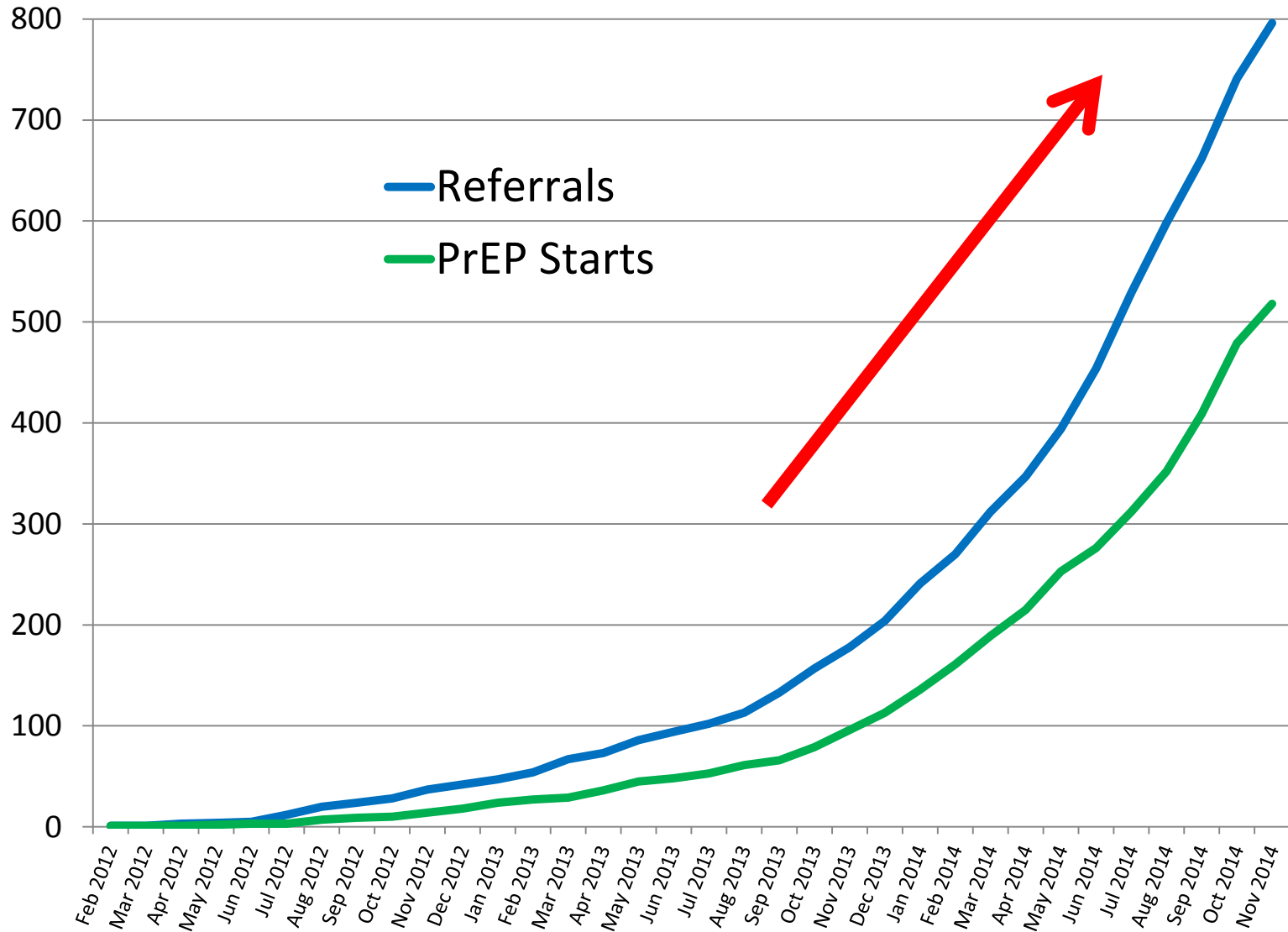
# Supporting PrEP uptake in SF

- SF Kaiser
- SF City Clinic PrEP navigation program
- San Francisco AIDS Foundation (Magnet)
- UCSF 360, SFGH Ward 86
- Bay Area Perinatal AIDS Center
- API Wellness, AHP, many other CBOs and clinics
- Getting to Zero PrEP Committee
- Clinician Consultation Center





# Kaiser PrEP Experience: 2012-2014



# PrEP Use by Sexual Practices in MSM: San Francisco, 2014

Condomless AI Partners last 6 months	Street Survey (% EVER on PrEP)	NHBS (% ANY PrEP In 12 mos)	SFCC (% CURRENT PrEP Use) <sup>1</sup>
0	9%	3%	8%
1	10%	4%	10%
2	11%	17%	16%
3-5	25%	30% <sup>2</sup>	33%
6 or more	63%		46%
<b>% on PREP</b>	<b>15.5%</b>	<b>10.1%</b>	<b>11.2%<sup>4</sup></b>
No. on PrEP		5,059	

1. SFCC asked specifically about condomless receptive anal intercourse partners.
2. NHBS collected detailed information on no more than 5 partners.
3. Percent using any PrEP in the past 12 months x 50,000 HIV negative population size.
4. Includes clients with missing data regarding ncRAI.

# Paying for PrEP



Coverage	How to access
Uninsured and < 500% FPL	<ul style="list-style-type: none"><li>• Gilead patient assistance program (PAP) provides TDF/FTC at no cost</li><li>• Client may need to pay for office visit and labs</li></ul>
Uninsured and > 500% FPL	<ul style="list-style-type: none"><li>• Pay out of pocket (\$1250/month) + office visits, lab costs</li></ul>
Medical	<ul style="list-style-type: none"><li>• Covered; No prior authorization</li></ul>
Employer-sponsored health insurance	<ul style="list-style-type: none"><li>• In general, most plans cover TDF/FTC for PrEP</li><li>• Cost sharing varies; Gilead offers \$300/month co-pay assistance</li><li>• Some require prior authorization, mail order Rx</li><li>• Provider needs to code visit correctly or q3mo HIV testing may not be covered</li></ul>
Covered California	<ul style="list-style-type: none"><li>• <b>Bronze:</b> High deductible, 30-40% co-pay for drugs after deductible met; <b>TDF/FTC approx \$800/mo (with co-pay assistance)</b></li><li>• Silver, Gold: Most have no cost after co-pay card</li></ul>

# SFDPH PrEP Navigation Services at SF City Clinic

- PrEP consultation, education and navigation
- Insured and has primary care:
  - Support and counseling about how to use insurance and access PrEP from PCP
- Uninsured or not in care:
  - PrEP initiation, health insurance navigation, linkage to care



# SFDPH PrEP Navigation Services at SF City Clinic

- Since May 2014, provided PrEP navigation to 450 clients and initiated >120 on PrEP
- 36% had previously received nPEP at the clinic
- 40.5% had a history of a syphilis, rectal gonorrhea or chlamydia in the prior year
- 43% insured (65% Medicaid, 35% other)
- 57% uninsured and enrolled in a medication assistance program (MAP)
- 38% of uninsured clients have enrolled in health insurance
- Younger and more diverse than Demo cohort



# SFDPH PrEP Navigation Services at SF City Clinic

	Demo Cohort (SFCC)	Clinic Cohort (SFCC)
Mean age	36	32
% < 26	15	25
Race/Ethnicity		
White	62	43
Black	3	8
Latino	21	29
Asian	6	15

# Linkage to Care

- Knowledge of health insurance eligibility, Affordable Care Act and local resources
- Gilead medication and co-pay assistance programs
- PrEP provider list: [www.hiveonline.org](http://www.hiveonline.org)

PrEP Provider Clinic/Institution Name	First Name	Last Name	Title	Address	City	State	ZIP Code	Telephone and Fax	Email	HIV Prevention / PrEP Information Website	Insurance Plans Accepted	Population Served
1. Sutter East Bay Medical Foundation	Drew	Ho	NP	500 San Pablo Avenue	Albany	CA	94706	510-204-8130	<a href="http://www.sebmf.org/locations/500_san_pablo.html">http://www.sebmf.org/locations/500_san_pablo.html</a>		PPO, HMO, Medical/Medicaid, Medicare, Contra Costa Health Plan	All men
2.	Frances	Herb	MD	2001 Dwight Way, Room 1388	Berkeley	CA	94704	510-981-4100			All	All are welcome
3. Solano County Family Health Services				2201 Courage Drive	Fairfield	CA	94533	707-784-2010	<a href="mailto:SR.Jones@solanocounty.com">SR.Jones@solanocounty.com</a>		Medi-Cal, Medicare, Partnership Healthcare	All are welcome
4. Tri-City Health Center				1999 Mowry Avenue, Suite F	Fremont	CA	94538	510-456-3522			Medi-Cal, Family PACT	All are welcome
5. Contra Costa Regional Medical Center				2500 Alhambra Avenue	Martinez	CA	94553	800-495-8885			CCHP, MediCal, Medicare	All are welcome
6. Asian Health Services				818 Webster Street	Oakland	CA	94607	510-986-8830 x371	<a href="mailto:ksakakibara@ahschc.org">ksakakibara@ahschc.org</a>		Alameda Alliance Medi-Cal, Blue Cross Medi-Cal, uninsured, Blue Cross and Blue Shield Covered CA plans, most Medicare plans	All are welcome
7. CRUSH Clinic				3100 Summit Street, 2nd Floor	Oakland	CA	94609	510-863-0021	<a href="mailto:crushoakland@gmail.com">crushoakland@gmail.com</a>	<a href="http://CRUSH510.org">CRUSH510.org</a>	This is a research project for young gay men ages 18 through 29. All services are free of charge for research participants	Transgender Women & Straight, Gay, & Bisexual Men
8. Lifelong Medical Care-East Oakland				10700 MacArthur Boulevard, Suite 14B	Oakland	CA	94609	510-932-1034	<a href="mailto:dgreenberg@lifelongmedical.org">dgreenberg@lifelongmedical.org</a>		Private, Medi-Cal, Medicare, Healthpac	All are welcome
9.	Andres	Marin		3451 East 12th Street	Oakland	CA	94601	510-535-3500			Medi-Cal, Medicare, AAH	All are welcome

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Keith Rawlings

## Study participants



University of California  
San Francisco





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# Questions and Discussion



# Characteristics of enrolled participants

- Mean age 35; 98% MSM
- 48% white, 35% Latino
- 34% < \$20K/year
- 37% uninsured
- 69% had heard of PrEP
- 54% self-referred
- Behavioral risk
  - 67% reported condomless RAS past 3 mo
  - 42% reported > 5 condomless anal sex partners past 12 mo
  - 15% reported meth use past 12 mo
- High prevalence of STDs at baseline
  - 4.5% early syphilis
  - 16.5% rectal GC or CT