

## THE DEMO PROJECT



Sexual Risk Behaviors and Sexually Transmitted Infections Among MSM participating in the US PrEP Demo Project

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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.

## Disclosures

- The US PrEP Demonstration Project was funded by the NIH
- Gilead Sciences provided study drug and supported drug level testing for this project

## Background

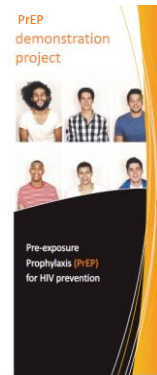


- Several RCTs have shown that daily oral TDF/FTC is effective in preventing HIV infection<sup>1-4</sup>
- Whether individuals taking PrEP will increase sexual risk behavior (i.e. risk compensation) is unclear
- PrEP demonstration projects, in which clients are educated about the efficacy of TDF/FTC and take it in an open-label fashion, are optimal settings for assessing whether risk compensation occurs

<sup>1</sup>Grant NEJM 2010; <sup>2</sup>Baeten NEJM 2012; <sup>3</sup>Thigpen NEJM 2012; <sup>4</sup>Choopanya Lancet 2013

## The Demo Project

- Multisite, open-label PrEP Demonstration Project in MSM and transgender women in two STD clinics and a community health center in the US
- Key objectives
  - PrEP uptake<sup>1,2</sup>
  - Adherence and retention<sup>1,3</sup>
  - Safety and tolerability<sup>3</sup>
  - HIV incidence and resistance<sup>3</sup>
  - **Sexual behaviors**
  - **STI incidence**



<sup>1</sup>Cohen S CROI 2014; <sup>2</sup>Cohen JAIDS 2015; <sup>3</sup>Liu IAS 2015

## Methods: Demo Project Sites

San Francisco City Clinic  
(N=300)



Whitman Walker Health,  
Washington, DC  
(N=100)

Miami-Dade County  
Downtown STD clinic (N=157)



Annual HIV seroconversion rate among MSM >2% across clinics

## Methods: Eligibility and follow-up

- HIV-negative MSM and transgender women enrolled between Oct 2012 - Jan 2014
- Behavioral risk criteria (last 12 mo):
  - Condomless anal sex with 2+ partners
  - 2+ episodes of anal sex with HIV+ partner
  - Self-reported diagnosis of syphilis, rectal gonorrhea or rectal chlamydia
- CrCl ≥ 60 ml/min, negative/trace protein on urine dipstick, HbSAg negative
- Participants offered up to 48 weeks of TDF/FTC PrEP
- Followed at weeks 4, 12, 24, 36 and 48 for HIV/STI testing, counseling, clinical monitoring, drug level testing and PrEP dispensation

## Methods: Assessment of sexual risk

- At screening and quarterly visits, participants completed an interviewer administered questionnaire regarding sexual and drug use behaviors, HIV risk perception, and serosorting intentions
- Composite measure of sexual risk assessed using modified "San Diego Early Test" (mSDET) Score<sup>1</sup>:

In the last 3 months -

- Any condomless receptive anal sex (CRAS) with HIV+ partner (3 points)
- Combination of any CRAS plus  $\geq 2$  male anal sex partners (3 points)
- $\geq 5$  male anal sex partners (2 points)

<sup>1</sup>Hoeningl CID 2015

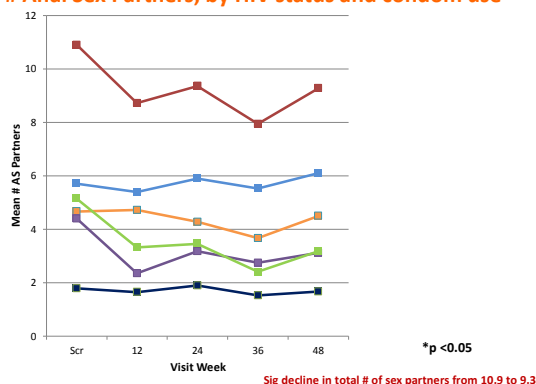
## Baseline characteristics of enrolled participants (N=557)

Characteristic	%
Age (median)	35 years with 20% <25 years
Race/ethnicity	
White	48%
Latino	35%
Black	7%
Other	10%
Gender	
Male	98%
Transgender	1.3%
Education level	
$\leq$ High School	15%
Some college or higher	85%
Any recreational drug use	74%
Popper, cocaine, meth, or club drug use	58%
Number of anal sex partners, past 3 months (mean)	1.1
Condomless receptive anal sex, past 3 mo	67%
HIV+ primary partner	24%
Lab confirmed STI (GC, CT, syphilis) at baseline	26%

## Methods: Statistical analysis

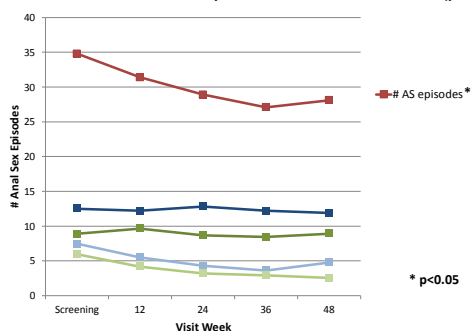
- Trends over time in absolute numbers of sexual partners and episodes, by partner HIV status, position and condom use were assessed using orthogonal contrasts in the weekly means, based on a Poisson regression model with robust standard errors to account for clustering by participant of the repeated outcomes.
- Covariate effects on changes in the mSDET scores were also estimated using Poisson models with robust SEs, using interactions between each covariate and an indicator for follow-up vs baseline.
- Heterogeneity across weeks in positivity of STI tests was assessed using logistic models with robust SEs to account for clustering.

## # Anal Sex Partners, by HIV status and condom use

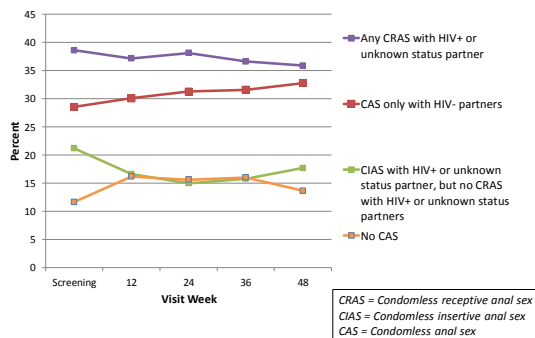


## # Insertive and Receptive Anal Sex Episodes, by condom use

Mean number of anal sex episodes declined from 34.8 to 28.1 (p=0.007)

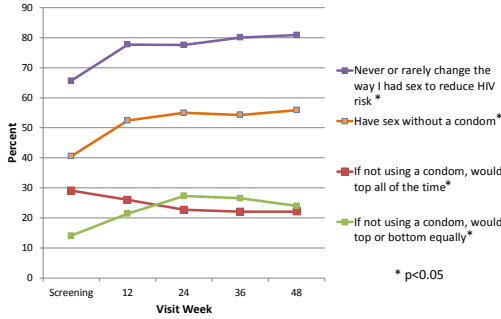


## Serosorting Practices

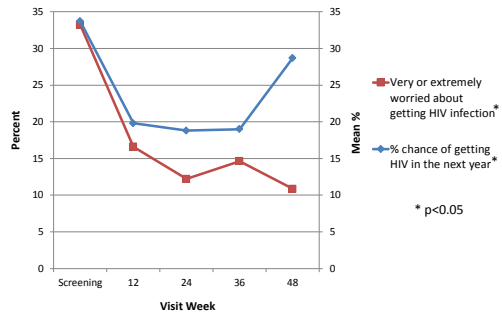


### Serosorting Intentions:

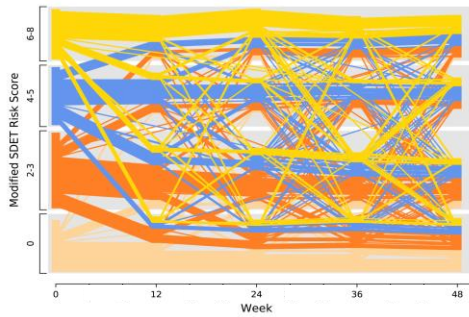
"When having sex with an HIV-positive partner I would..."



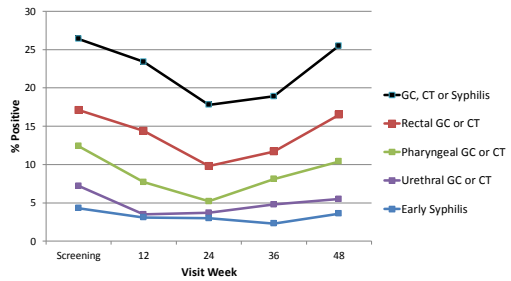
### HIV Risk Perception



### Change in overall risk as measured by mSDET risk score



### Results: STI positivity



50.9% of participants had at least one STI during follow-up  
 Overall STI incidence (90/100 person years) stable across quarterly intervals (P>0.1)  
 As expected, >75% of GC and >85% of CT infections were asymptomatic

### Limitations

- Sexual risk behavior collected by interviewer-administered questionnaire, subject to social desirability bias
- Observational cohort with no comparison group
- Non-differential follow-up by level of risk could bias results
- Blacks and transgender women underrepresented
- Results may not generalize to broader MSM populations in these or other US cities, international settings
- Demo Project provided risk reduction counseling at each quarterly visit, may not apply in settings in which counseling not offered

### Conclusions

- By multiple measures, including number of anal sex partners, episodes and a composite sexual risk score, sexual risk behavior was stable or declining over the course of the study.
- While self-reported behaviors did not reflect a change in seroadaptive practice, intentions around seroadaptation did change; over time, this could have implications for sexual networks and STI risk.
- 50% of participants had a variation in risk score from visit to visit – re-assessing risk among clients using PrEP is important.
- High incidence of STIs reflects importance of comprehensive sexual health support and quarterly STI screening, including testing at extragenital sites, for MSM taking PrEP.

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### Study participants



## mSDET Score (distribution and mean) over time

