Sexually Transmitted Diseases in the Biomedical HIV Prevention Era

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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 and support for drug level testing for the US PrEP demo project.
- Dr. Cohen serves as an unpaid public health advisor to the Gilead HIV PrEP Steering Committee

Roadmap

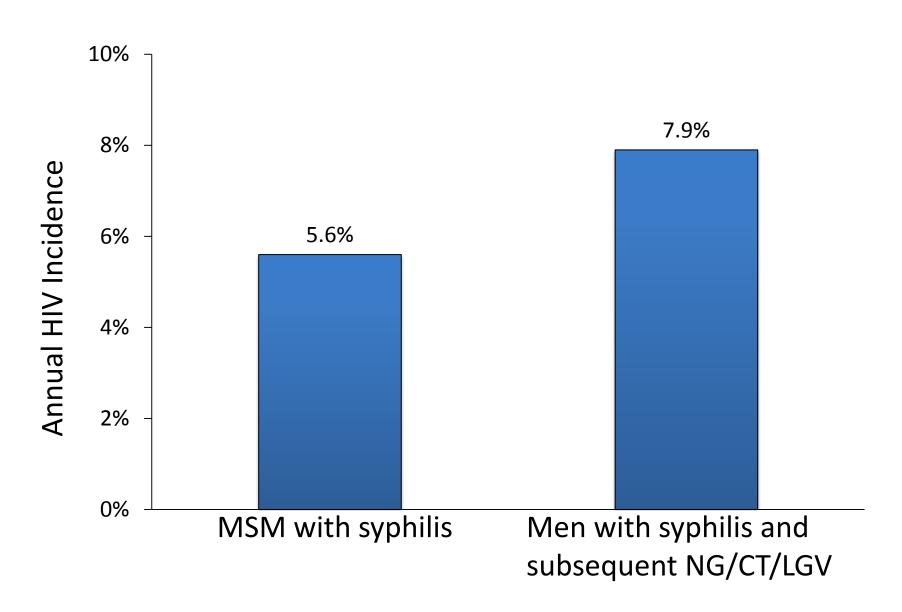
- Review epidemiology of HIV and STDs among men who have sex with men (MSM)
- Discuss data on impact of PrEP on sexual behaviors and STD incidence
- Reflect on STD prevention in the biomedical HIV prevention era

Epidemiologic Synergy

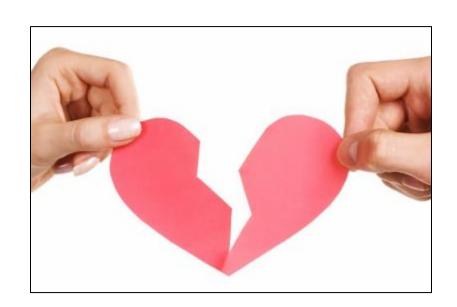


- 85% of cases of HIV occur through sexual transmission
- STDs increase risk of HIV acquisition and transmission
 - Reduce physical and mechanical barriers to viral entry
 - Increase number and density of HIV-1 receptor-positive cells via inflammation
 - Imbalance of protective vaginal flora
 - Increase HIV concentrations in plasma, genital lesions or secretions

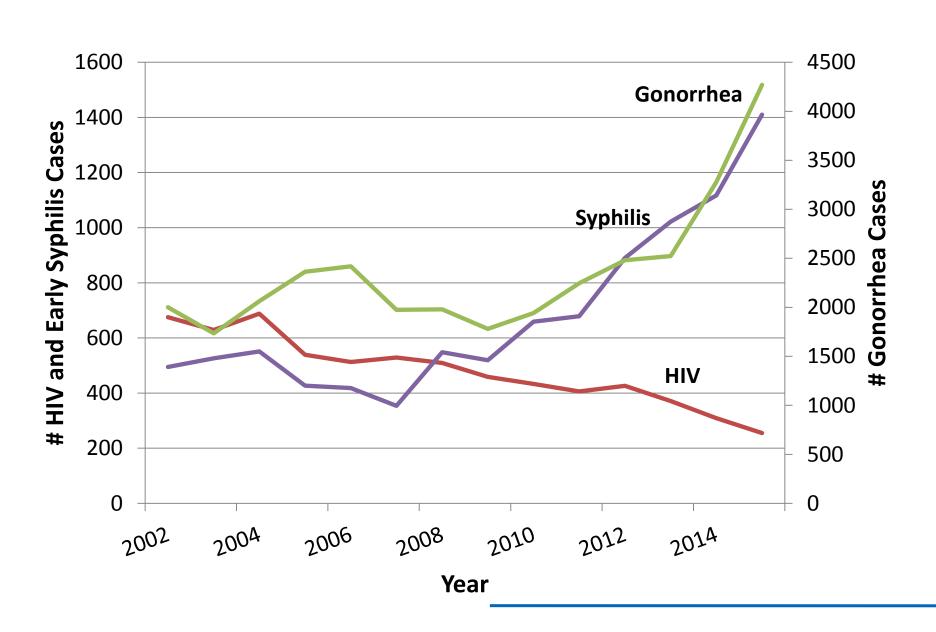
Prior STD = elevated risk for HIV



An Epidemiologic Divide



HIV and STDs in San Francisco, 2002-2015



Pre-Exposure Prophylaxis and Treatment as Prevention

- Partner-independent HIV prevention methods
 - totally controlled by the user
 - independent of the state of mind immediately prior to and during sex

Highly effective, even in the presence of a concurrent STD

PrEP and Risk Compensation



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618 Doctors & Advocates Agree

Thank you to the 618 individuals who have signed letters to the U.S. Food & Drug Administration (FDA) and to drug maker Gilead Sciences' CEO John Martin asking for a halt to FDA approval for expanded use of the company's AIDS treatment drug Truvada as an HIV prevention pill – also known as pre-exposure prophylaxis or PrEP.

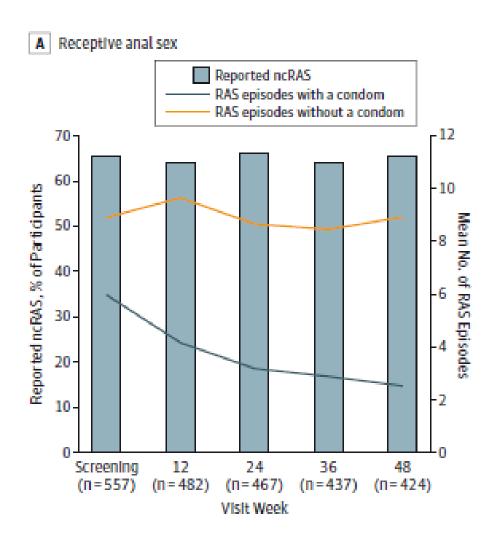
Truvada is not ready for widespread use as an HIV prevention pill because:

- In the largest study, Truvada was only 44% effective at preventing HIV.
- · There is a lack of "real world" data.
- There could be an increased risk to men who falsely believe they are protected from HIV and stop using condoms.

Join the chorus: Ask Gilead Sciences to stop pursuit of FDA approval for Truvada as PrEP until further study is completed.

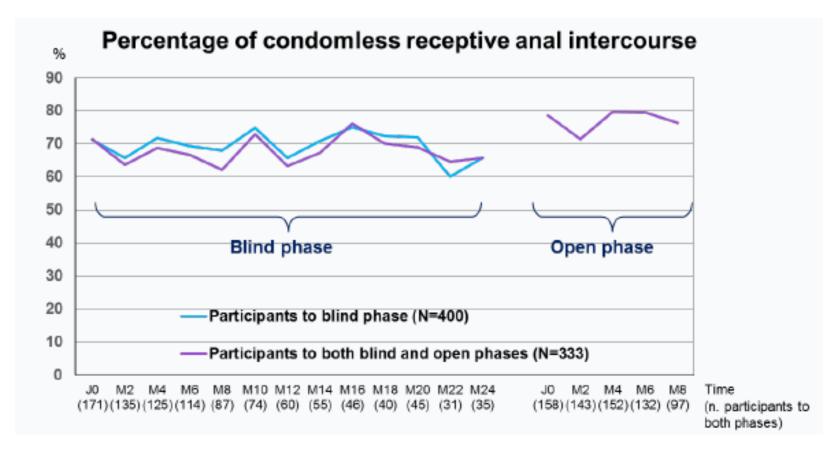
- Risk Compensation = Theory that people adjust behavior in response to perceived level of risk
- Has been assessed in regards to bike helmets, seat belts, air bags, condoms, contraception
- One of the most commonly cited concerns about PrEP by clinicians and clients

US PrEP Demonstration Project



- High STD positivity rates (26%) at baseline
- 50% had at least one
 STD during follow-up
- STD rate did not increase during followup

Risk Compensation Ipergay (Open Label)



- No change in median number of sexual partners or episodes of anal sex
- Increase in % of receptive anal sex episodes that were condomless

STDs in IPERGAY



Sexually Transmitted Infections

	Double-Blind Median FU: 9.3 months n=400		Open-Label Median FU: 18.4 months n=362	
	Nb Pt (%)	Nb Cases	Nb Pt (%)	Nb Cases
Chlamydiae	81 (20)	114	122 (34)	158
Gonorrheae	88 (22)	123	117 (32)	175
Syphilis	39 (10)	45	68 (19)	77
HCV	5 (1)	5	5 (1)	5
All STIs	147 (37)	287	210 (58)	415

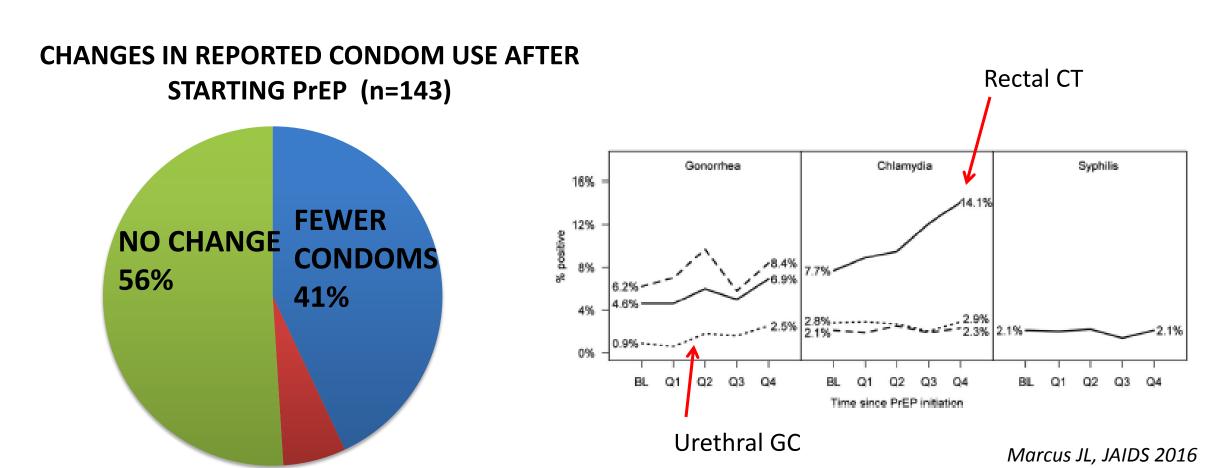




35.2 vs 40.6 per 100 PY in the double-blinded and OLE phases



KP RISK COMPENSATION DATA



MORE CONDOMS 3%

Volk et al. CID 2015

What do people want from sex and PrEP?

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KQED Forum, "STD Rates in California Soar." Host: Mina Kim. October 27, 2016

What do people want from sex and PrEP?

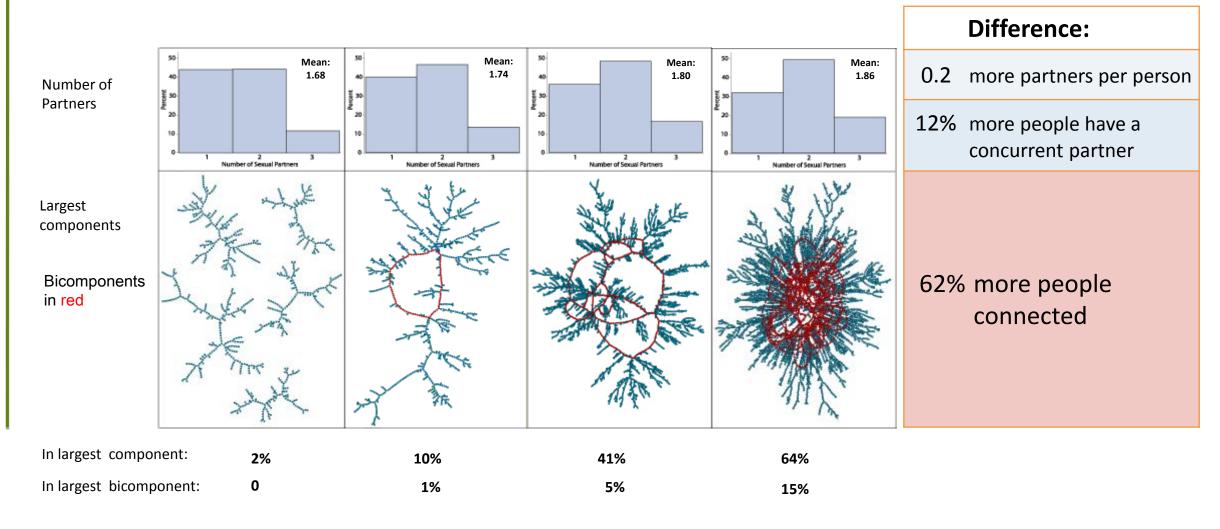
- Pleasure
- Intimacy
- Trust
- Reduced anxiety around sex
- Agency and empowerment
- Lessened stigma

- "When it comes down to it, it happens. It's a part of sex...It's a concern, but I know it's going to happen, I know the way to treat it, and you move on from there."
- "It's just like, go get tested every 2 months or so. If you have something, they'll treat it right away and then it's gone and then nothing happened, you know what I mean? There's like, no change whatsoever. So why worry about it?"

Grant Curr Opinion HIV/AIDS 2016; Hughes S Med Anthro in press; Trainor N R4P 2016

SFDPH MSM Focus Groups 2014

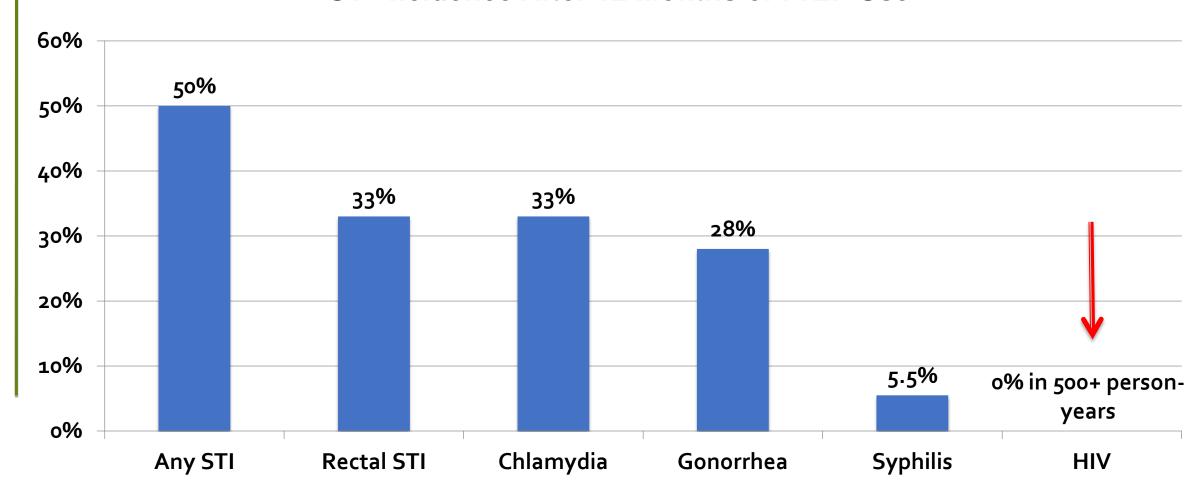
More partners = more connectivity



Despite high rates of STDs, few HIV infections in setting of PrEP

Kaiser Cohort: High rates of STI infections, but no HIV infections on PrEP

STI Incidence After 12 Months of PrEP Use



US PrEP Demo Project: High rates of STIs, very few HIV infections

- Despite high incidence of STIs,
 very low incidence of HIV
- Only 2 HIV infections both with low/undetectable drug

Infection	Incidence (per 100 PYs)
Gonorrhea	42.8 (95% CI 37-49)
Chlamydia	48.2 (95% CI 42-55)
Syphilis	12.4 (95% CI 9-16)
HIV	0.4 (95% CI 0.05-1.5)

PrEP – Not only for HIV?

- Caprisa 004
 - Intervention: Tenofovir intravaginal gel 12 hours pre and post sexual contact in high risk South African women
 - 55% reduction in HSV-2 seroconversion
- Partners PREP
 - Heterosexual HIV-negative partners in HIV discordant partnerships in Africa randomized to truvada, tenofovir, or placebo
 - 30% reduction in HSV-2 acquisition

Counseling about STD Prevention in the Biomedical HIV Prevention Era

• Engage clients in a conversation about their overall sexual health goals

Emphasize that PrEP does not prevent other STDs

Recommend q3mo STD screening

Address other drivers of risk, including substance use and mental health issues

STD Prevention for MSM in the Biomedical HIV Prevention Era

- Screen and treat
 - Express visits; self-collected specimens
 - Point of care tests to decrease time to treatment
 - Provider focused interventions
- Partner treatment

- Condom availability
- Innovation
 - PrEP for STDs?
 - Vaccines
- Decrease stigma
 - LGBTQ rights
 - Decriminalization of HIV

Conclusions

- HIV-negative MSM with rectal STDs or syphilis should be initiated on PrEP
- Some evidence of risk compensation in PrEP demonstration projects and clinical cohorts
 - Does not attenuate the efficacy of PrEP for HIV prevention
 - Reported condom use was declining and STD rates were increasing prior to PrEP
 - # of individuals currently on PrEP not enough to explain all the STD increases
 - PrEP offers opportunities for "prevention synergy"
- Need innovative STD prevention tools and new strategies to motivate clients around STD prevention

Capacity Building Assistance in High-Impact HIV Prevention for Health Departments

Our team includes nationally-recognized experts specializing in HIV Testing, Prevention for High-Risk Negative Individuals, and Policy.

Our philosophy: Provide customized, peer-to-peer TA, with a focus on engagement in person and online, by utilizing creative and innovative technologies.

Contact Us!

Visit: www.getSFcba.org

Call: 415.437.6226

Email: get.SFcba@sfdph.org



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Promoting Sexual Health Through STD Prevention

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- Trang Nguyen

Study participants





Patients







Getting to Zero PrEP Committee



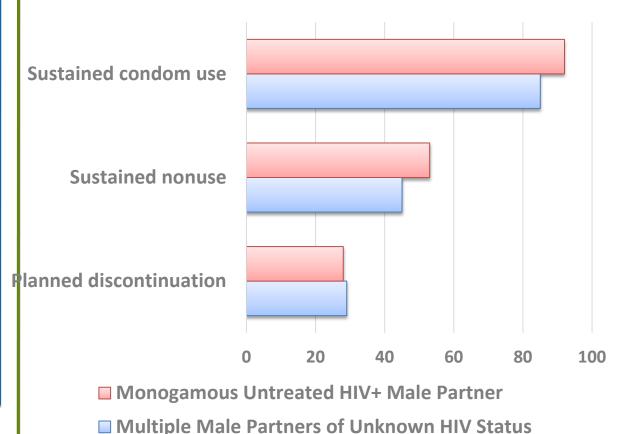






Provider Beliefs Cloud Judgment Around Prescribing PrEP

% Medical Students Willing to Prescribe PrEP



Reasons for d/c condoms	% reporting acceptable
Conception	69%
Intimacy/emotional connection	23%
Pleasure	14%
Sexual functioning	13%

Ppts were more willing to prescribe PrEP to monogamous MSM vs. MSM with multiple partners for 2/3 condom conditions

Adapted from Calabrese S R4P Chicago 2016; Slide courtesy Al Liu

More STDs = More Complicated STDs

Sexually Transmitted Diseases (STDs) > Syphilis > Treatment and Care

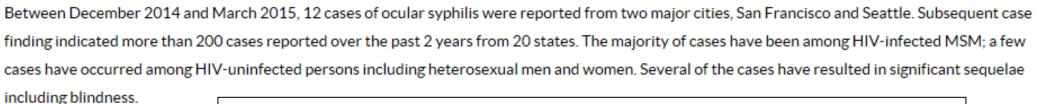
Clinical Advisory: Ocular Syphilis in the United States











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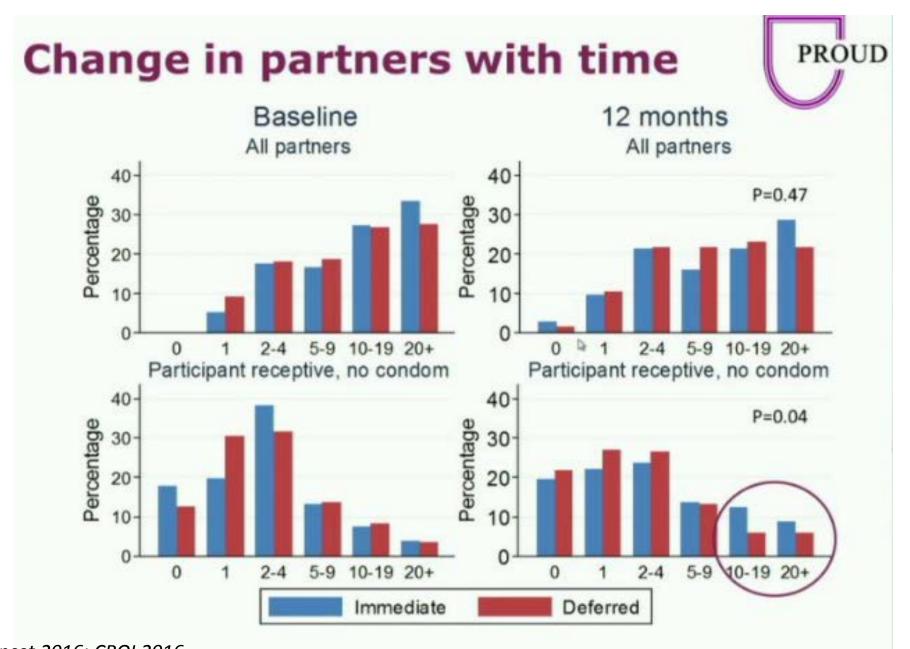
CDC: Drug-resistant gonorrhea cases found in Hawaii

Associated Press

September 22, 2016

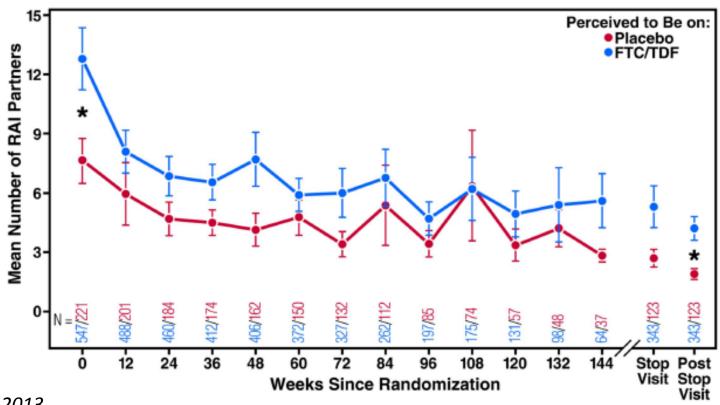
Updated September 22, 2016 8:57am





PrEP and Risk Compensation

 In iPrEx, belief in receiving FTC/TDF was not associated with an increase in numbers of RAI sex partners or % of condomless RAI sex partners



STD incidence for MSM on PrEP higher than MSM not on PrEP, but may be due to several factors

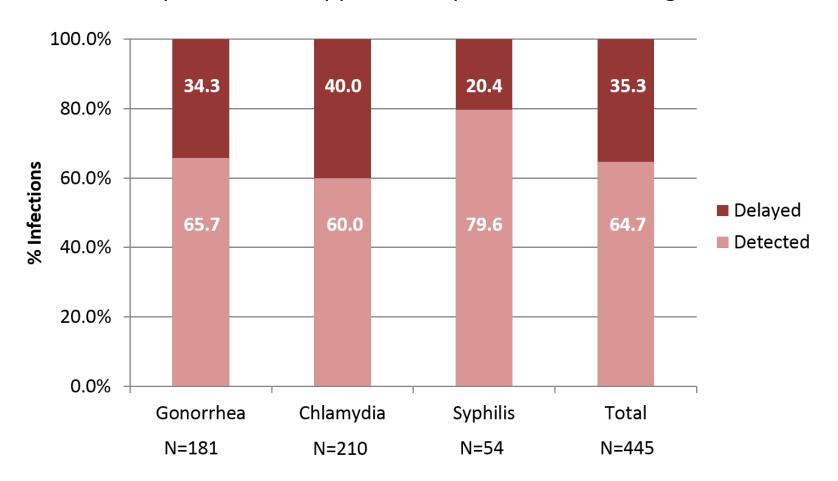
STIs	MSM using PrEP STI incidence / 100 py	MSM not using PrEP STI incidence / 100 py	Incidence Rate Ratio
Any GC infection	37.5	4.2	25.3
Any CT infection	38.0	6.6	11.2
Syphilis	14.5	0.9	44.6

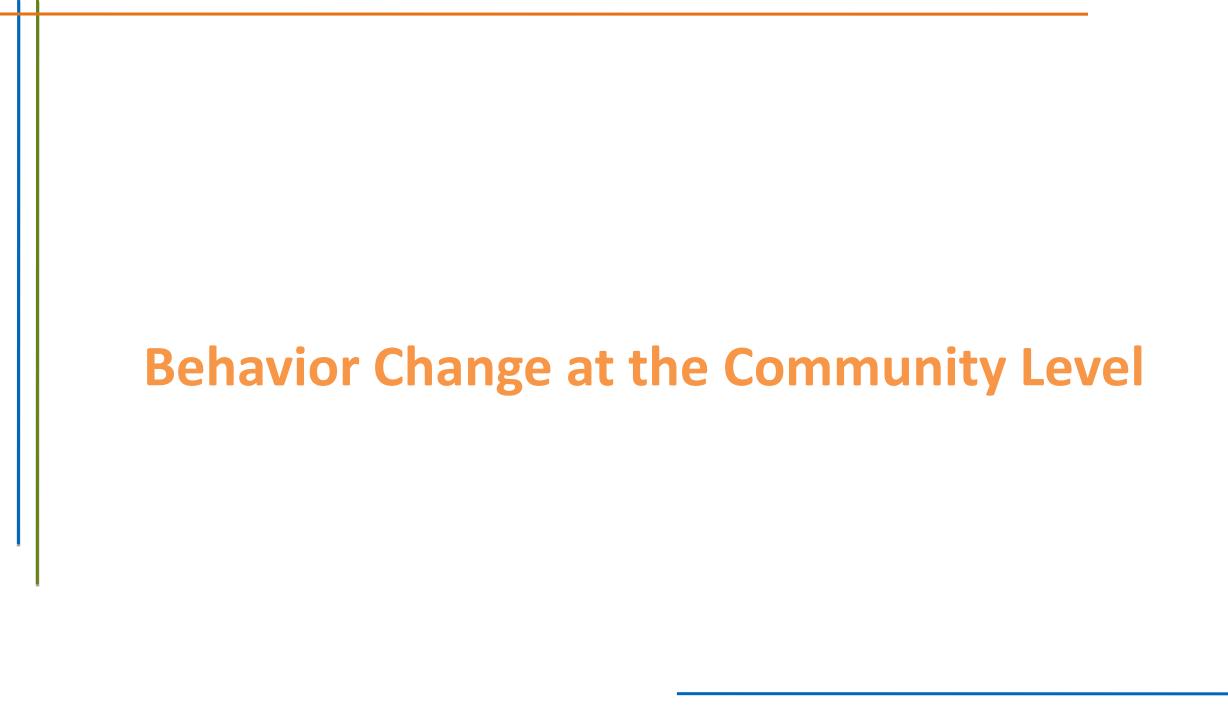
Potential reasons for higher STD rates among PrEP users:

- PrEP cohorts recruit MSM at high risk for STDs
- STD screening more frequent in PrEP cohorts
- STD incidence increasing over time, & PrEP cohorts include more recent samples
- Risk compensation

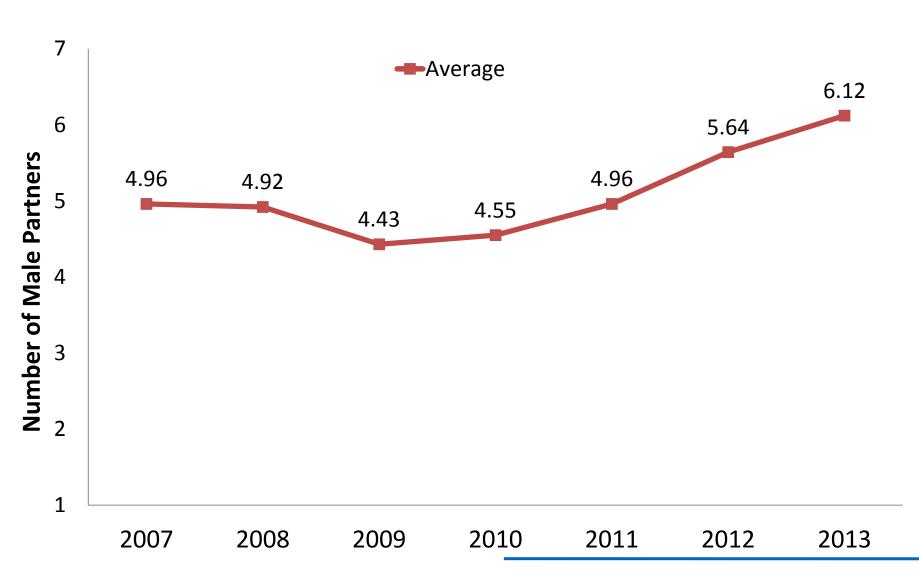
STDs among PrEP users in PrEP Demo

% infections for which treatment would have been delayed with q6 month, as opposed to q3 month, screening

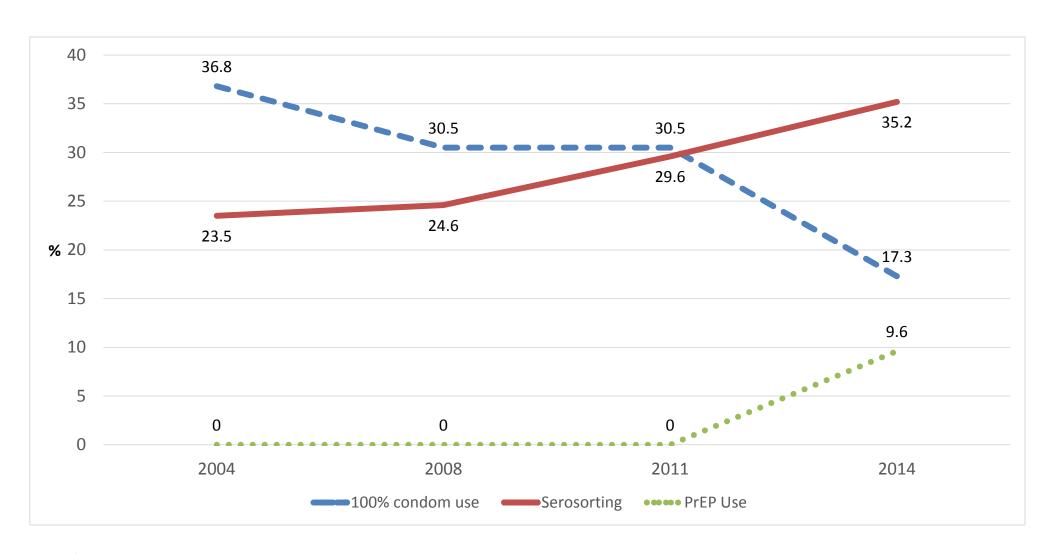




Average Number of Male Sex Partners in Prior 3 Months Among MSM Patient Visits, SF City Clinic 2007-2013



National HIV Behavioral Surveillance: San Francisco MSM



Modeling suggests regular STI screening/treatment as part of PrEP delivery can reduce STI incidence by preventing onward transmission



