

# Special Presentation: DoxyPEP update





# TRANSLATING EVIDENCE INTO ACTION FOR PUBLIC HEALTH: THE DOXY-PEP STORY



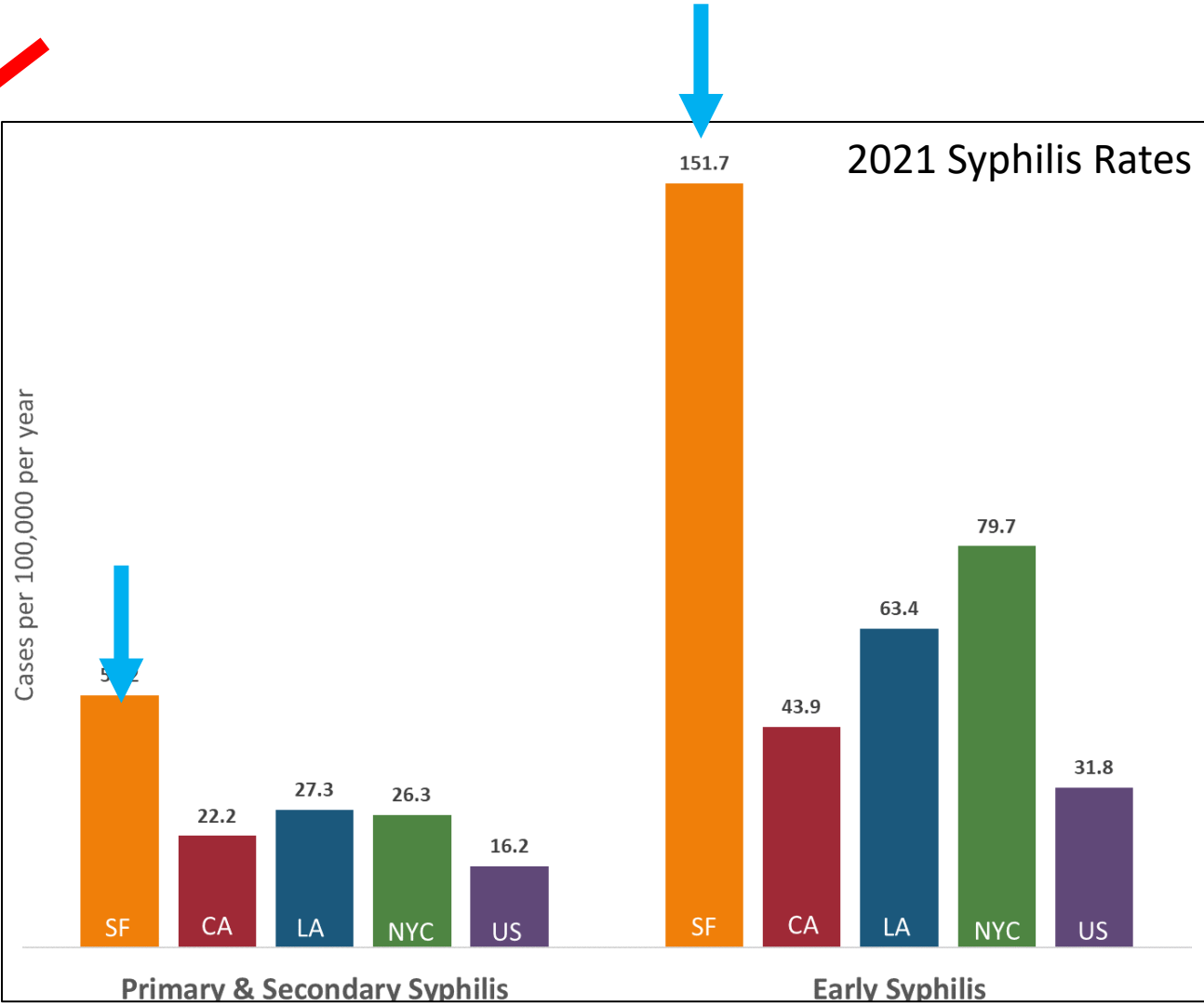
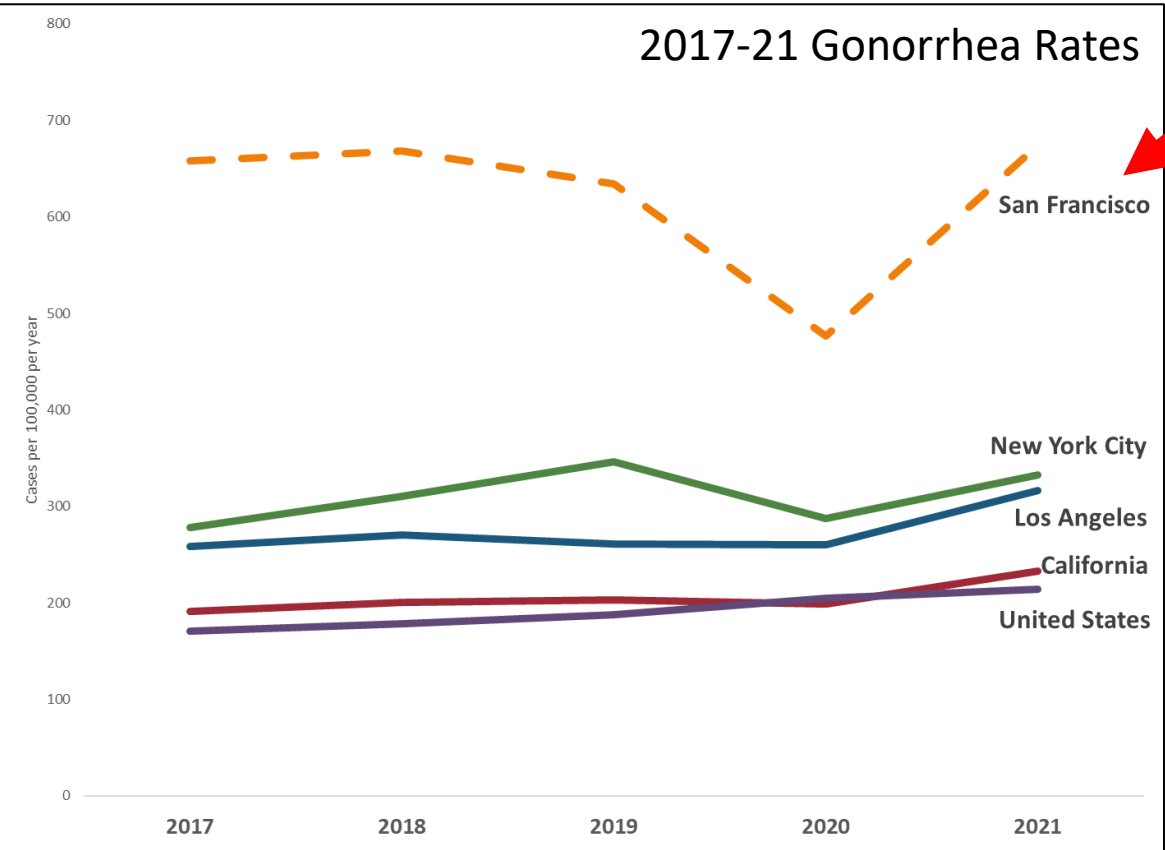
CDC/HRSA Advisory Committee (CHAC)  
April 10, 2024

Stephanie Cohen, MD, MPH  
Director, HIV/STI Prevention Section  
SF Department of Public Health

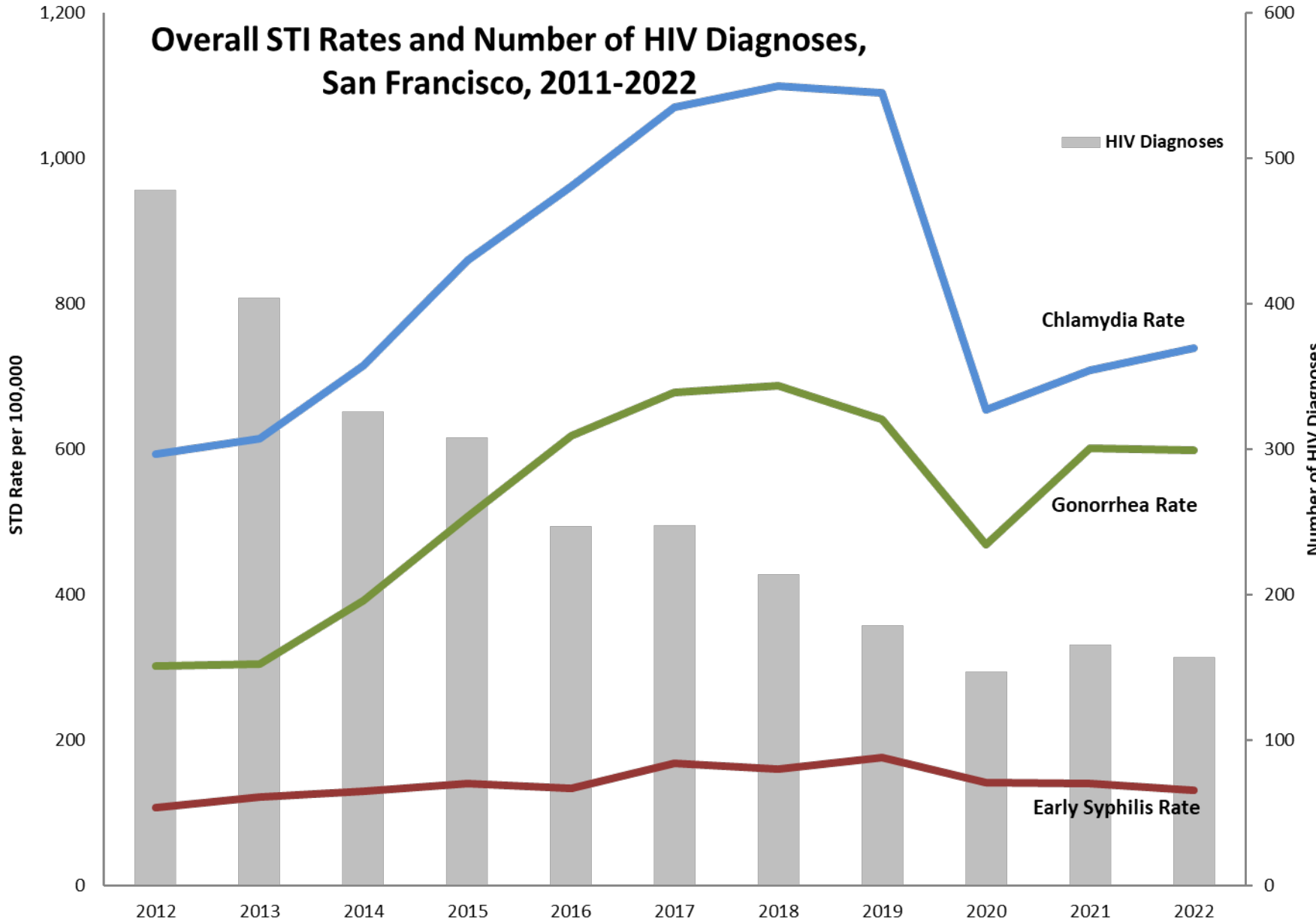


**POPULATION HEALTH DIVISION**  
SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

San Francisco has higher chlamydia, gonorrhea, and syphilis rates compared to the United States overall, the state of California, Los Angeles and New York City.



# Overall STI Rates and Number of HIV Diagnoses, San Francisco, 2011-2022



2014 to 2019:	
Chlamydia	76%
Gonorrhea	72%
Early Syphilis	45%

# In November 2019, US DoxyPEP study launched in San Francisco and Seattle

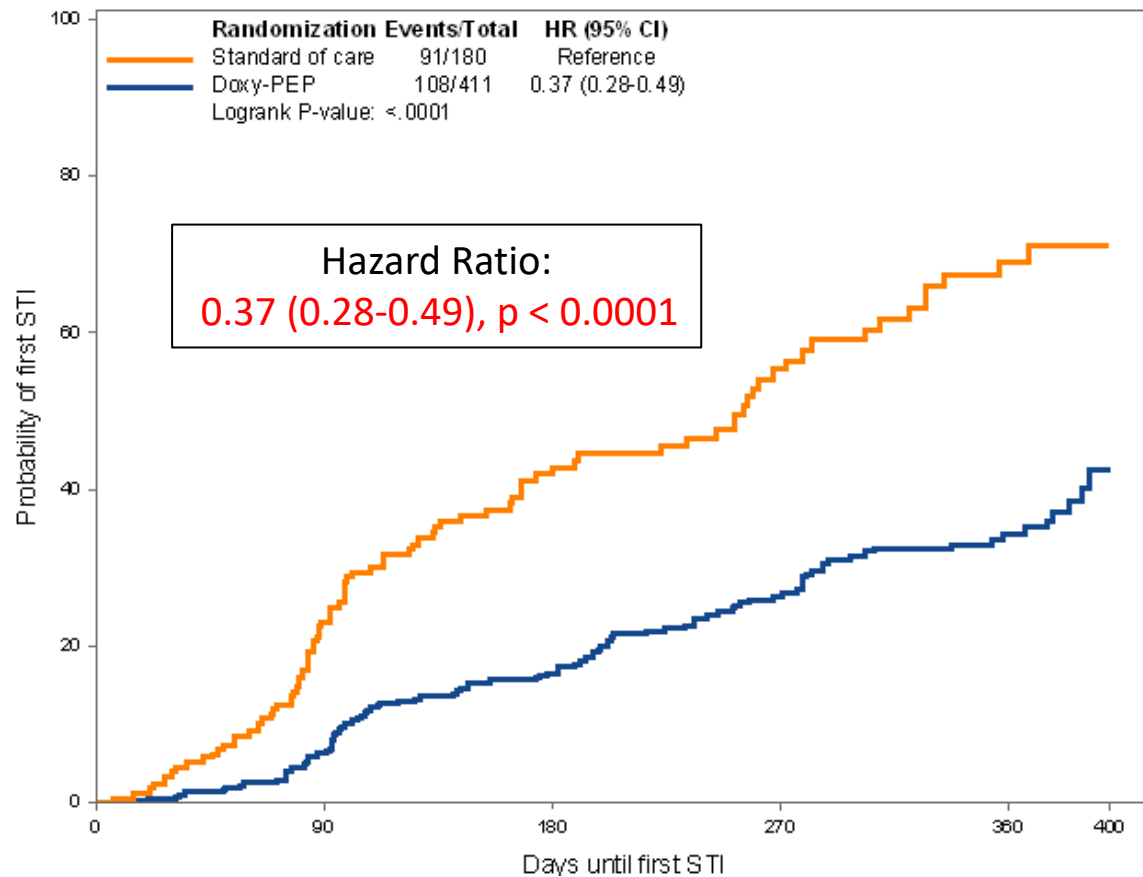
## Why Doxycycline (doxy)?

- Safe, well tolerated, inexpensive oral antibiotic
- Active against chlamydia & syphilis. Approx 80% of gonorrhea strains in US susceptible
- Shown to reduce STIs in two prior studies
  - Small pilot in LA (N=30) of doxy pre-exposure prophylaxis (PrEP)
  - Ipergay study in France (N=232) of doxy post exposure prophylaxis (PEP)
- Strong interest amongst men who have sex with men (MSM)
- US DoxyPEP study, French DOXYVAC and Kenya D-PEP studies aimed to assess the impact of doxy-PEP on bacterial STIs incidence *and* on drug resistance (in STIs and other bacteria)

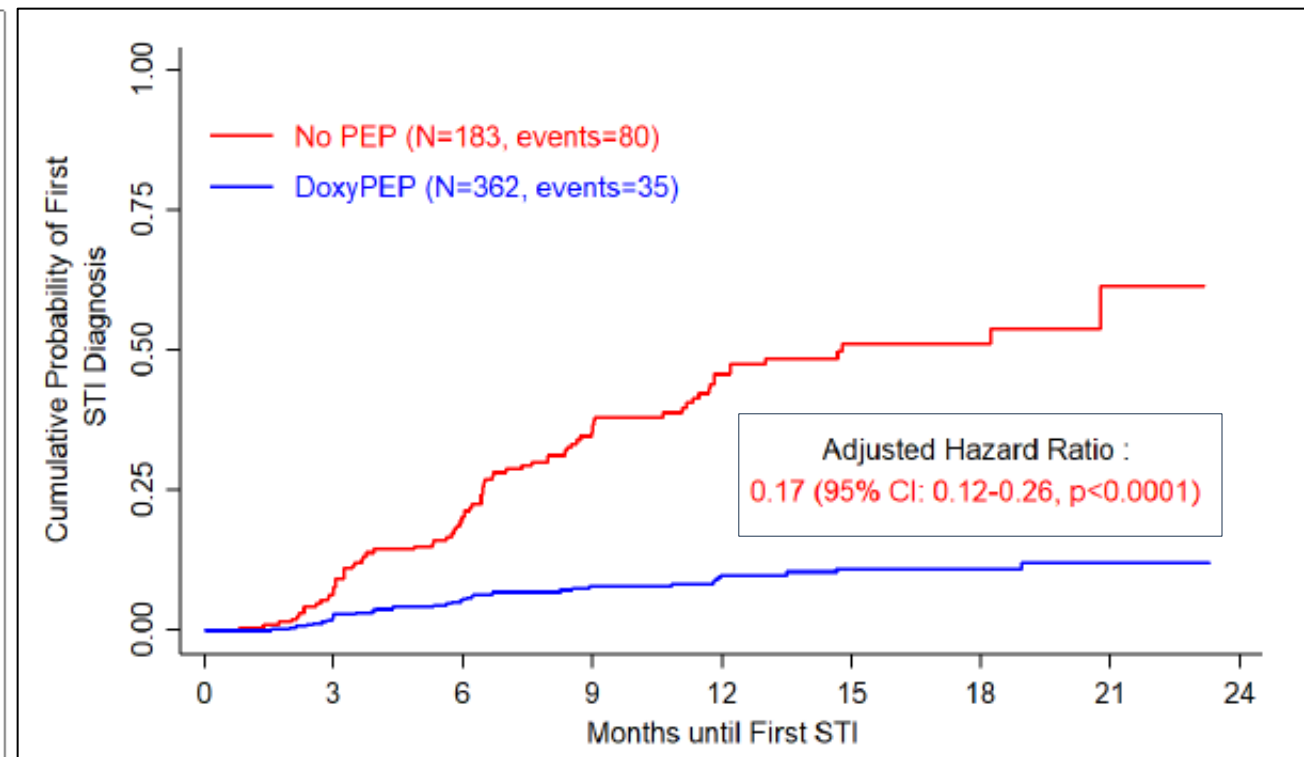


# DoxyPEP and DOXYVAC studies demonstrated substantial reduction in risk of bacterial STIs in MSM and trans women

Time to first CT, GC or syphilis: DoxyPEP<sup>1</sup>



Time to first CT or syphilis: DoxyVAC<sup>2</sup>

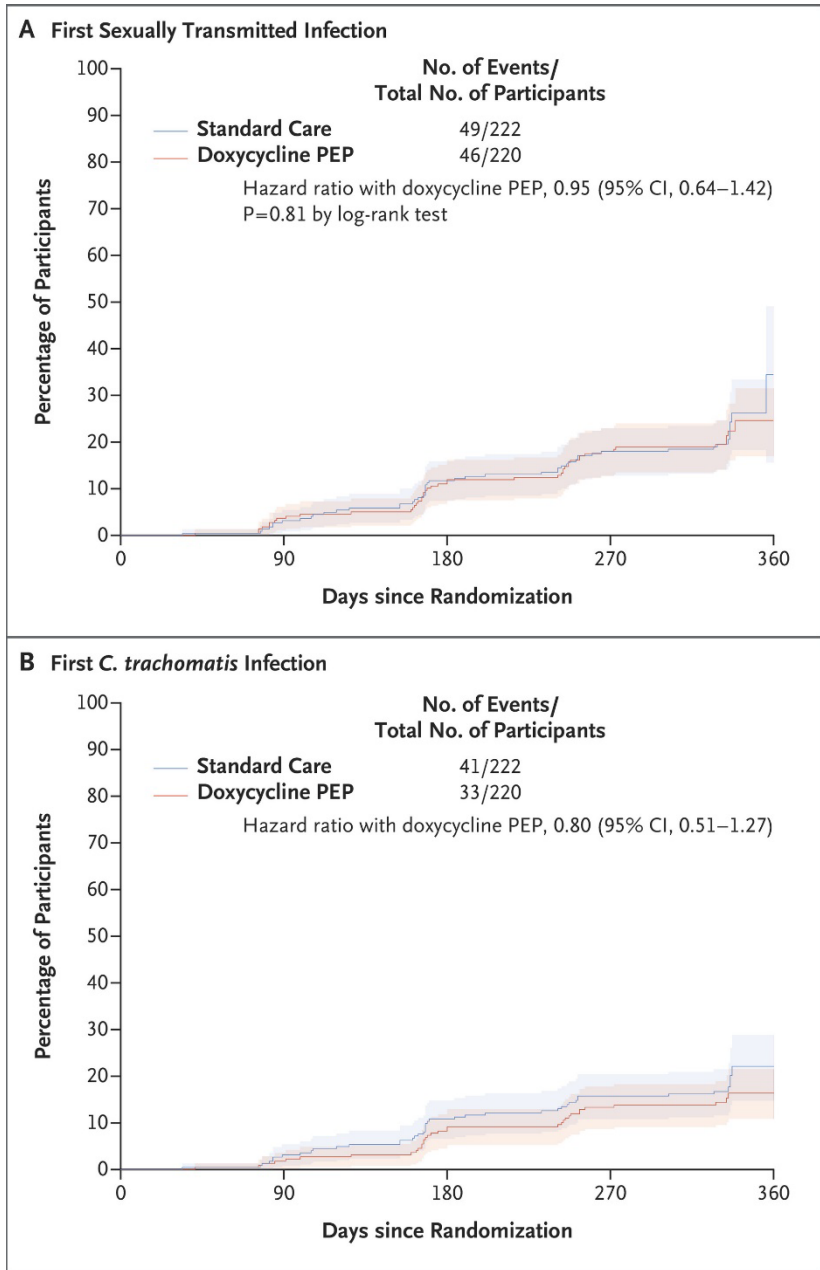


<sup>1</sup>DoxyPEP, Luetkemeyer et al, NEJM 2023; 388:1296-1306, <sup>2</sup>DOXYVAC, Molina et al, CROI 2024



# Kenya D-PEP study *did not* find that doxy-PEP reduced STIs in cis women

- High self-reported adherence ( $\geq 80\%$ )
- Median 4 doses per month (IQR 0-8)
- Low hair drug levels in women in doxycycline group suggest low adherence to doxy-PEP



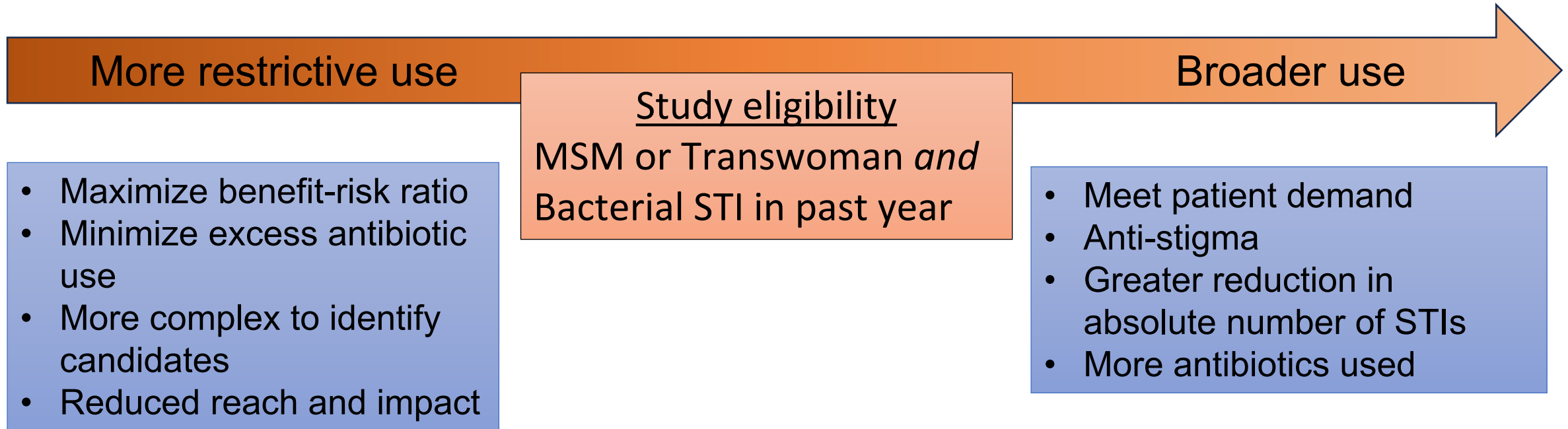
# How to implement doxy-PEP in San Francisco?

- Eligibility criteria
- Supporting roll-out and uptake
- Monitoring impacts of doxy-PEP
  - Disparities in uptake
  - STI rates
  - Antimicrobial resistance
  - Adverse events (e.g effect on microbiome)





# Who Should be Offered Doxy-PEP?



# SFDPH: First jurisdiction in US to release guidelines for DoxyPEP



POPULATION HEALTH DIVISION  
SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH



## 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 [considerations](#) 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.

# Doxy-PEP

## Interim Guidelines



POPULATION HEALTH DIVISION  
SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH



### Health Update

## Doxycycline Post-Exposure Prophylaxis Reduces Incidence of Sexually Transmitted Infections

October 21, 2022

- 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  $\geq 1$  cis male or trans female partner in the past year. 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. Results from the Kenya D-PEP study found that doxy-PEP was *not* effective at preventing STIs among cis women.** Drug level data suggest that this may have been due to low adherence to doxy-PEP. Providers can consider offering doxy-PEP to cis women on a case-by-case basis, for example to women with a history of syphilis or women who exchange sex for money or drugs.

# Readable, concise, non-stigmatizing patient and provider facing education in multiple languages

## About Doxy-PEP



### What is doxy-PEP?

- Doxy-PEP means taking the antibiotic doxycycline after sex, to prevent getting an STI. It is like a morning-after pill but for STIs. Taking doxy-PEP reduces your chance of acquiring syphilis, gonorrhea, and chlamydia by about two-thirds.

### When should I take doxy-PEP?

- Two 100 mg pills of doxycycline should be taken after condomless sex. Condomless sex means isn't used for the entire time.

### What about when I have sex again?

- If you have sex again within 24 hours of taking last dose. You can take doxycycline as often as you don't take more than 200 mg (two 100 mg pills).

### How should I take doxy-PEP?

- Take doxycycline with plenty of water or some you swallow. If your stomach is upset by doxy-PEP, some people are more sensitive to the sun.
- Please do not share doxycycline with others.
- Avoid dairy products, calcium, antacids, or iron.

### What are we still learning about doxy-PEP?

- Does it affect normal ("good") bacteria in our bodies?
- Could it increase or decrease the bacteria that cause STIs (for example, chlamydia, gonorrhea, and syphilis)?
- Will doxy-PEP increase doxycycline resistance?
  - Although doxycycline has been used for decades to treat chlamydia and syphilis.
  - About 25% of gonorrhea in the US is already resistant to doxycycline. The DoxyPEP study and other studies are testing if doxy-PEP changes resistance in gonorrhea.

### Reminders

- Call us at 628-217-6692 if you run out of doxy-PEP or think you may have an STI.
- Please continue to get tested for STIs every 3 months.
- Doxy-PEP doesn't protect against MPX (monkeypox).



## Acerca de Doxy-PEP



### ¿Qué es doxy-PEP?

- El doxy-PEP significa tomar el antibiótico doxiciclina después de las relaciones para prevenir contraer una infección de transmisión sexual (ITS). Es como una pastilla del día después pero para las ITS. Tomar doxy-PEP reduce la probabilidad de contraer sífilis, gonorrea y clamidia en aproximadamente dos tercios.

### ¿Cuándo debo tomar doxy-PEP?

- Se toma dos pastillas de doxiciclina de 100 mg dentro de las 24 horas, pero a más tardar 72 horas después de tener relaciones sexuales sin condón. Las relaciones sin condón significa las relaciones orales, anales o vaginales/con agujero delantero, en las que no se usa un condón todo el rato.

### ¿Y qué pasa si vuelvo a tener relaciones?

- Si vuelve a tener relaciones dentro de las 24 horas después de tomar doxiciclina, tome otra dosis 24 horas después de la última dosis. Puede tomar doxiciclina tan frecuentemente como todos los días cuando esté teniendo relaciones sin condón, pero no tome más de 200 mg (dos pastillas de 100 mg) cada 24 horas.

### ¿Cómo debo tomar doxy-PEP?

- Tome la doxiciclina con abundante agua o algo más para beber para que no se atase al tragar. Si la doxiciclina le produce malestar estomacal, puede ser útil tomarla con alimentos.
- Algunas personas son más sensibles al sol cuando toman doxiciclina, así que use protector solar.
- No comparta la doxiciclina con otras personas.
- Evite los productos lácteos, el calcio, los antácidos o las multivitaminas dentro de las 2 horas antes o 2 horas después de tomar doxiciclina para una absorción óptima de doxiciclina en el cuerpo.

### ¿Qué estamos aprendiendo todavía sobre doxy-PEP?

- ¿Afecta las bacterias normales ("buenas") en nuestros intestinos?
- ¿Podría aumentar o disminuir las bacterias que viven en nuestra piel, o hacerlas resistentes a la doxiciclina?
- ¿Doxy-PEP aumentará la resistencia a la doxiciclina en las bacterias que causan las ITS?
  - Aunque la doxiciclina se ha utilizado durante décadas, no parece haber resistencia a la doxiciclina en la clamidia ni en la sífilis.
  - Alrededor del 25% de la gonorrea en los EE. UU. ya es resistente a doxy-PEP; doxy-PEP puede no funcionar contra estas cepas. El estudio DoxyPEP, y otros estudios científicos, nos ayudarán a comprender si el uso de doxy-PEP cambia la resistencia en la gonorrea.

### Recordatorios

- Llámenos al 628-217-6692 si se le acaba la doxiciclina, si tiene algún efecto secundario o si cree que puede tener una ITS.
- El doxy-PEP reduce la posibilidad de contraer sífilis, gonorrea y clamidia, pero estas ITS aún pueden ocurrir. Continúe haciéndose la prueba a intervalos regulares y si tiene síntomas.
- Doxy-PEP no protege contra MPX (viruela del mono), VIH u otras infecciones virales.



## Doxy-PEP fact sheet for healthcare providers in San Francisco

### What is doxy-PEP?

Doxycycline post-exposure prophylaxis (doxy-PEP) is using **doxycycline 200 mg within 72 hours after oral, anal, or vaginal sex to prevent the acquisition of chlamydia, gonorrhea, and syphilis.**

A recent study showed doxy-PEP was effective among men who have sex with men (MSM) and trans women living with HIV (62% reduction in acquisition) or taking HIV PrEP (65% reduction).<sup>1</sup> Efficacy against other bacterial sexually transmitted infections (STIs) is not known, and doxy-PEP does not prevent HIV, monkeypox (mpox), or other viral infections.

### Who can take doxy-PEP?

Recommend doxy-PEP to **gay, bisexual, and other MSM and trans women** who:

- have had condomless sex with  $\geq 1$  cis man or trans woman in the past year, and
- have had an STI in the past year.

Offer doxy-PEP using shared decision-making to **cis men, trans women, trans men, and other gender diverse patients** who:

- have had condomless sex in the past year with  $\geq 2$  cis men or trans women regardless of STI history.

**More data is needed on the efficacy of doxy-PEP in cis women.**

The only study to date among cis women did not find doxy-PEP effective at preventing STIs, possibly due to adherence.<sup>2</sup> If prescribing doxy-PEP to cis women due to STI risk factors like multiple STIs or sex work, discuss lack of efficacy data and advise not to use when pregnant.

### Dosing and prescribing guidance

- 200 mg of doxycycline taken as soon as possible** after condomless oral or anal sex, but **no later than 72 hours afterward.**
- Doxycycline can be taken every day** depending on frequency of sexual activity, but **no more than 200 mg within a 24-hour period.**
- Acceptable formulations:**
  - Doxycycline hyclate or monohydrate **immediate release 100 mg** (2 tabs taken together)
  - Doxycycline hyclate **delayed release 200 mg** (1 tab), but typically much costlier
- Example Rx:** doxycycline 100 mg, #60, 1 refill, take 2 capsules (200 mg) by mouth as needed ASAP after condomless sex, and no later than 72 hours after. Do not take more than 200 mg in a 24-hour period.
- ICD-10 diagnosis code Z20.2** (Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission).

Healthcare providers in San Francisco

### How often should I monitor patients taking doxy-PEP?

Screen for gonorrhea and chlamydia at all anatomic sites of exposure, and HIV (if not known to be living with HIV).

If a patient is **diagnosed with an STI while using doxy-PEP**, they should be treated according to standard CDC STI treatment guidelines ([www.bit.ly/STI\\_guides](http://www.bit.ly/STI_guides)).

**When using doxy-PEP reports:**

- Report to a sexual partner with syphilis:** epi-treat for syphilis per standard of care.
- Report to a sexual partner with gonorrhea or chlamydia:** consider waiting on treatment until test results are back using shared decision-making with patient.

### How should I counsel patients taking doxy-PEP?

Take doxycycline with fluids and remain upright for 30 minutes after the dose to reduce heartburn. Taking doxycycline with food may increase tolerability.

Be aware of **photosensitivity.** Patients should be counseled to wear sunscreen and/or avoid prolonged sun exposure while taking doxycycline.

Be aware of **doxy-PEP during pregnancy.** Patients who could get pregnant should receive counseling and be counseled to stop doxycycline if they become pregnant.

Be aware of a rare risk of benign intracranial hypertension and other serious side effects.

Be aware of unknown risks of doxy-PEP related to the microbiome and antibiotic resistance.

For more information in our patient-facing counseling handout and dosing instructions.

### How do I refer patients to comprehensive sexual health services?

Refer patients to **PrEP to all sexually active people** if they are not already taking it. Options include oral PrEP, 2-1-1 PrEP, and injectable PrEP.

Refer **people living with HIV are in care** and inform patients that maintaining an undetectable HIV viral load eliminates the risk of transmitting HIV to sexual partners.

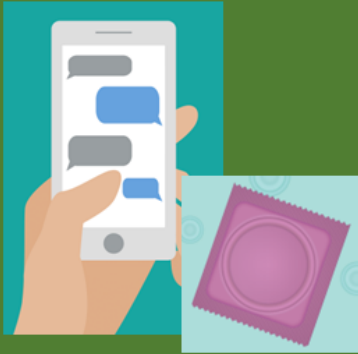
Screen for gonorrhea and chlamydia (using urine, pharyngeal, and rectal swabs) and syphilis, regardless of HIV serostatus.

STI **services should be offered for eligible individuals.** These could include mpox (monkeypox), meningococcal (MenACWY), hepatitis A, hepatitis B, and HPV.

For more **clinical guidance**, visit our website ([sfccityclinic.org](http://sfccityclinic.org)): [www.bit.ly/doxy-PEPupdate](http://www.bit.ly/doxy-PEPupdate) or contact Alyson Decker: [alyson.decker@sfdph.org](mailto:alyson.decker@sfdph.org)

1. AF, et al. Postexposure Doxycycline to Prevent Bacterial Sexually Transmitted Infections. *N Engl J Med*. 2023; 388:1296-1306.  
2. Doxycycline Prophylaxis to Prevent Bacterial Sexually Transmitted Infections in Women. *N Engl J Med*. 2023; 389(25):2331-2340.

# Doxy-PEP as part of a comprehensive package of sexual health services



## Primary prevention

- Education
- Condoms
- Risk reduction counseling
- Contraception



## Vaccines

- Hepatitis A & B
- HPV
- Mpox
- Meningococcal Vaccine (ACWY)



## PEP, PrEP and TASP

- HIV PEP
- HIV PrEP (Daily, 2-1-1, LA-injectable)
- Doxy-PEP**
- Linkage to ART



## Secondary prevention

- STI Screening & Treatment
- Partner Services



## Address social determinants of health

- Mental health & Substance Use treatment
- Anti-Poverty
- Anti-Racism
- Access to care



## Policy

- Reproductive rights
- LGBTQ rights
- Criminal justice reform



# SF City Clinic began offering doxy-PEP in November 2022

- SF City Clinic (SFCC) is a nationally-recognized center of excellence in sexual health services
- Offers integrated HIV, STI and reproductive health care grounded in a syndemic approach
- Drop-in and appointments available
- High Volume: 17,000 visits annually
- Serve a diverse population
  - 39% B/AA or Latino, 15% Asian
  - 40% <30 years
  - 50% LGBTQ



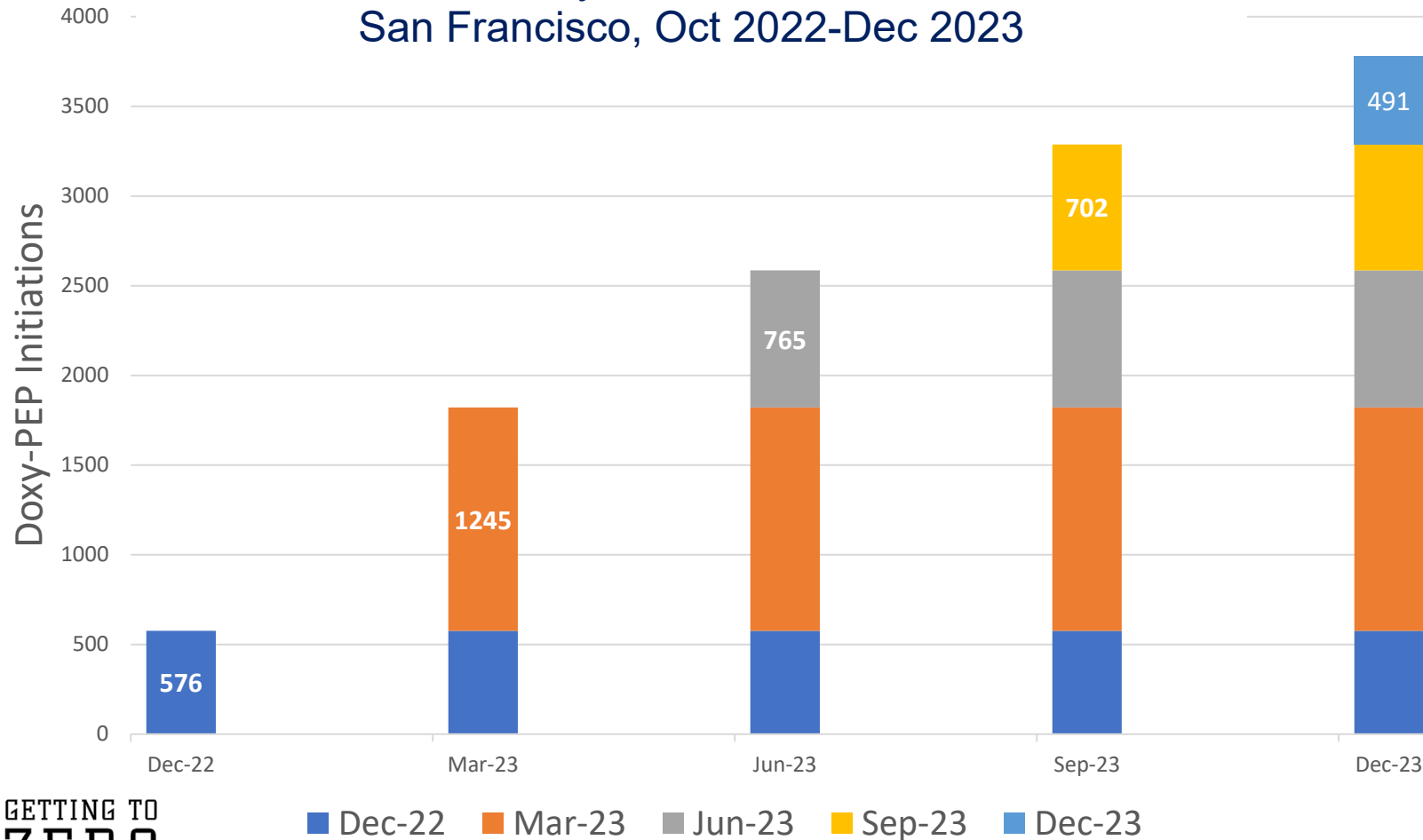


# High uptake of doxy-PEP at SFCC

- At SF City Clinic, MSM and TGW are systematically informed about doxy-PEP at PrEP initiation or PrEP follow-up
- Between November 2022 and May 2023:
  - 74% of patients with GC, CT or syphilis in prior year started doxy-PEP
  - 60% of patients with  $\geq 2$  sex partners, but no STI history started doxy-PEP
  - Uptake was associated with having a higher # of sex partners in prior 3 months; not with demographic factors

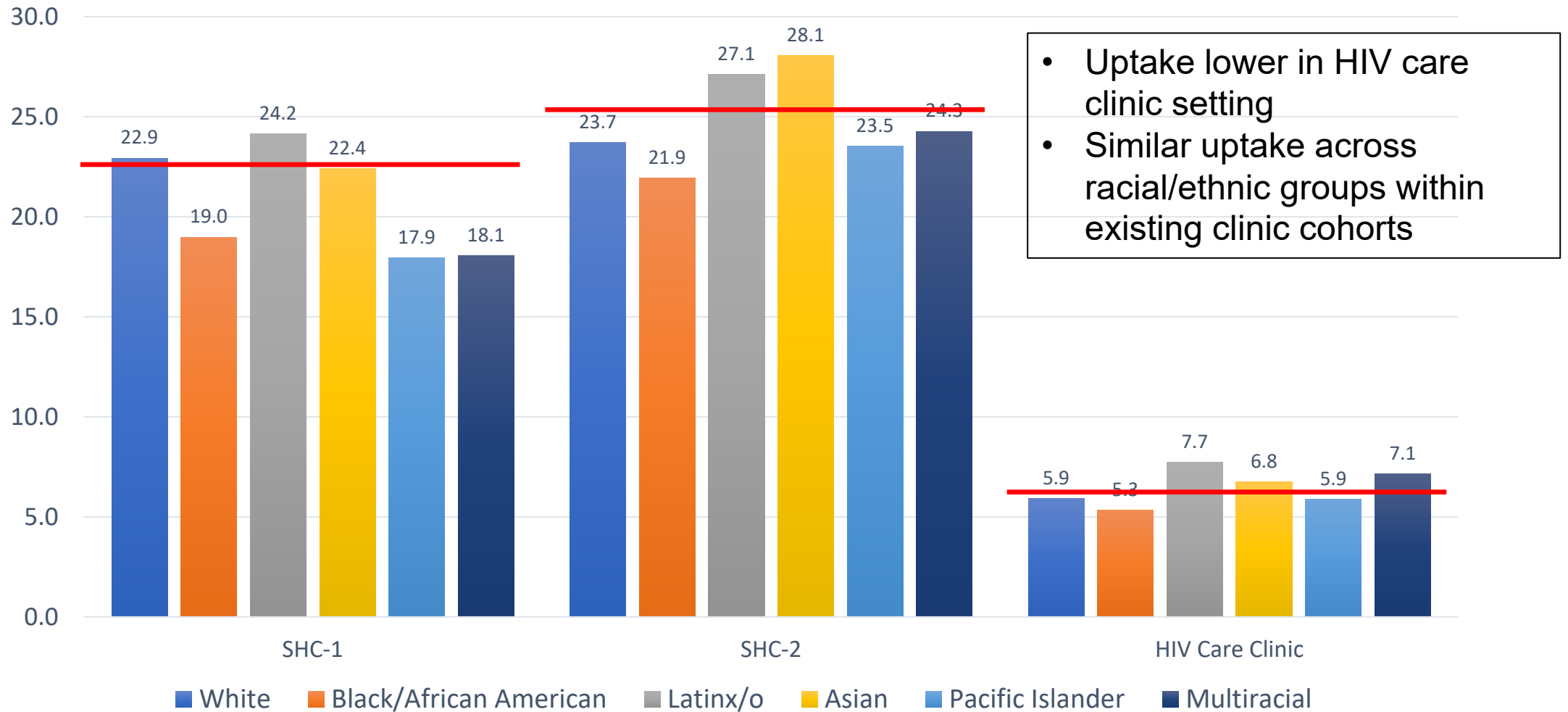
# High uptake of doxy-PEP in San Francisco after release of guidelines

3779 Cumulative Doxy-PEP Initiations Across 3 Clinics, San Francisco, Oct 2022-Dec 2023



- Sentinel surveillance at 1 safety-net HIV clinic and 2 sexual health clinics
- High volume health maintenance organization and primary care clinics not included

# Doxy-PEP Uptake by Race/Ethnicity at 2 Sexual Health Clinics (SHC) and 1 HIV Care Clinic San Francisco, Oct 2022 – Dec 2023



# Decline in chlamydia and syphilis among PrEP patients receiving doxy-PEP at sexual health clinics in SF

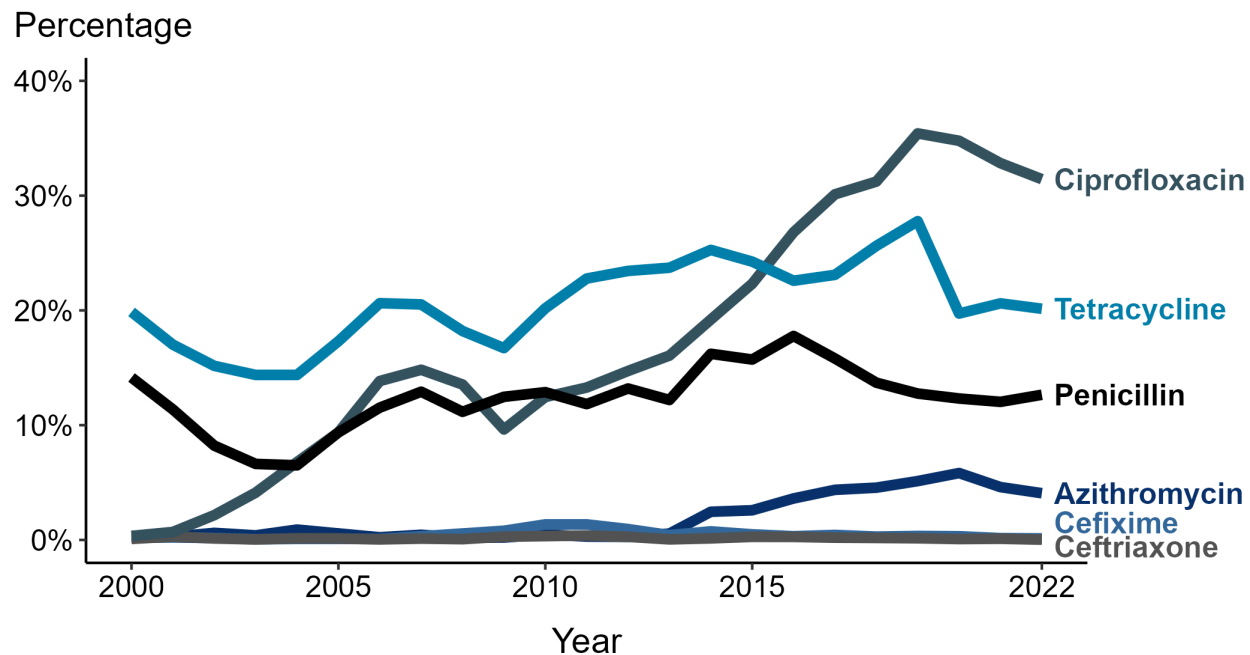
	CBO-run sexual health clinic 6/1/22-9/1/23	Municipal sexual health clinic 11/3/21-10/30/23
Chlamydia	<b>67% decrease</b> [IRR: 0.33, 95% CI: 0.23-0.46]	<b>90% decrease</b> [RR: 0.10, 95% CI: 0.05-0.21]
Syphilis	<b>78% decrease</b> [IRR 0.22, 95% CI: 0.09-0.54]	<b>56% decrease</b> [RR 0.44, 95% CI 0.21-0.92]
Gonorrhea	11% decrease [IRR 0.89, 95% CI 0.69-1.15]	23% decrease [RR 0.77, 95% CI 0.58–1.02]



Monitoring for antimicrobial resistance,  
adverse events, patient experience

# Surveillance systems to monitor for anti-microbial resistance

*Neisseria gonorrhoeae* — Prevalence of Tetracycline, Penicillin, or Ciprofloxacin Resistance\* or Elevated Cefixime, Ceftriaxone, or Azithromycin Minimum Inhibitory Concentrations (MICs)†, by Year — Gonococcal Isolate Surveillance Project (GISP), 2000–2022

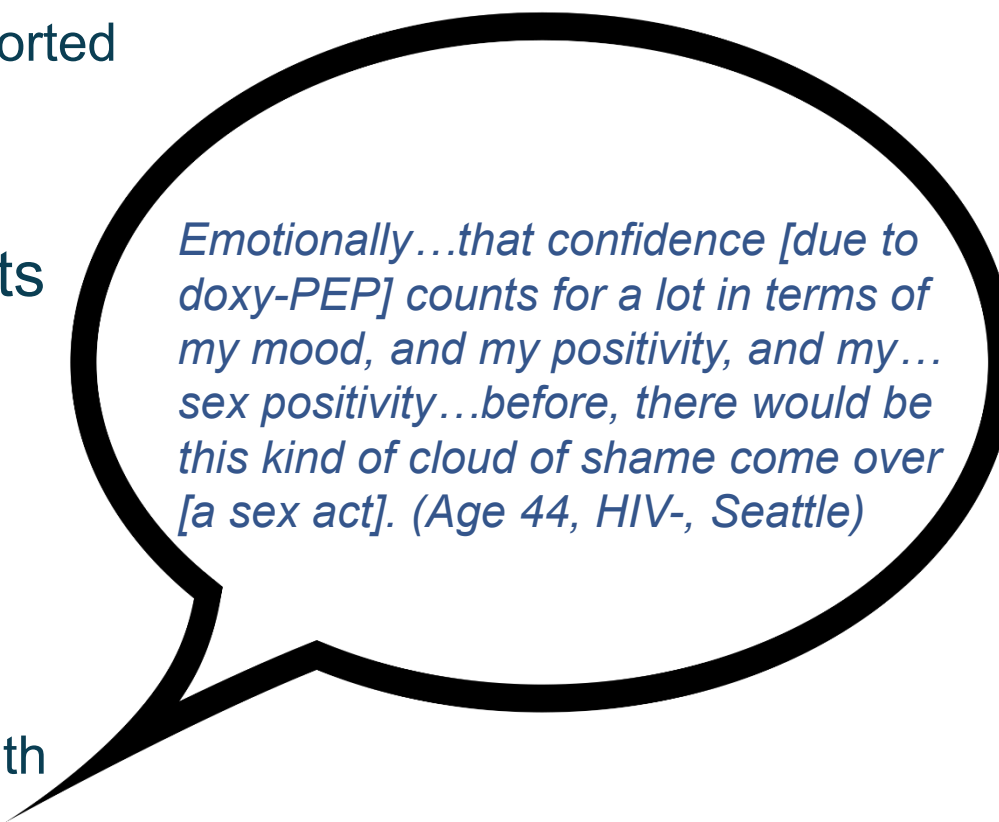


- CDC supports sentinel surveillance for culture-based GC antibiotic susceptibility testing
- Need systems for monitoring non-STI pathogens, including staph aureus, strep pneumo and E. coli
- Challenging to discern specific impacts of doxy-PEP in context of overall doxycycline use in medicine and agriculture



# Patient Experience and Adverse Events

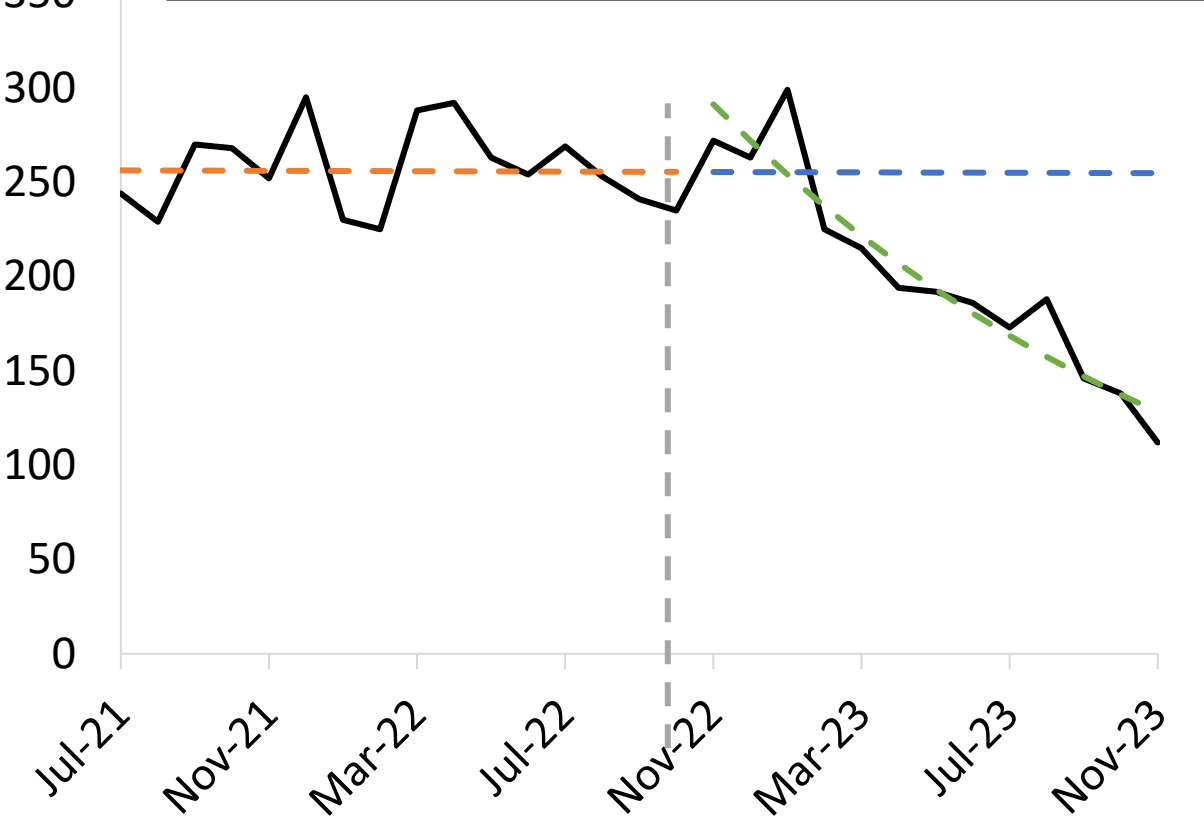
- Patients report using doxy-PEP selectively
  - At follow-up visits, 89% of those prescribed doxy-PEP reported using it, but not with every condomless sex act
- Occasional discontinuations related to GI side effects
- Sex-positive and person-first intervention
  - Improved peace of mind and sexual pleasure
  - Decreased stigma around STI diagnosis and disclosure
  - Increased self-awareness about sexual behavior
  - Facilitates communication with partners about sexual health



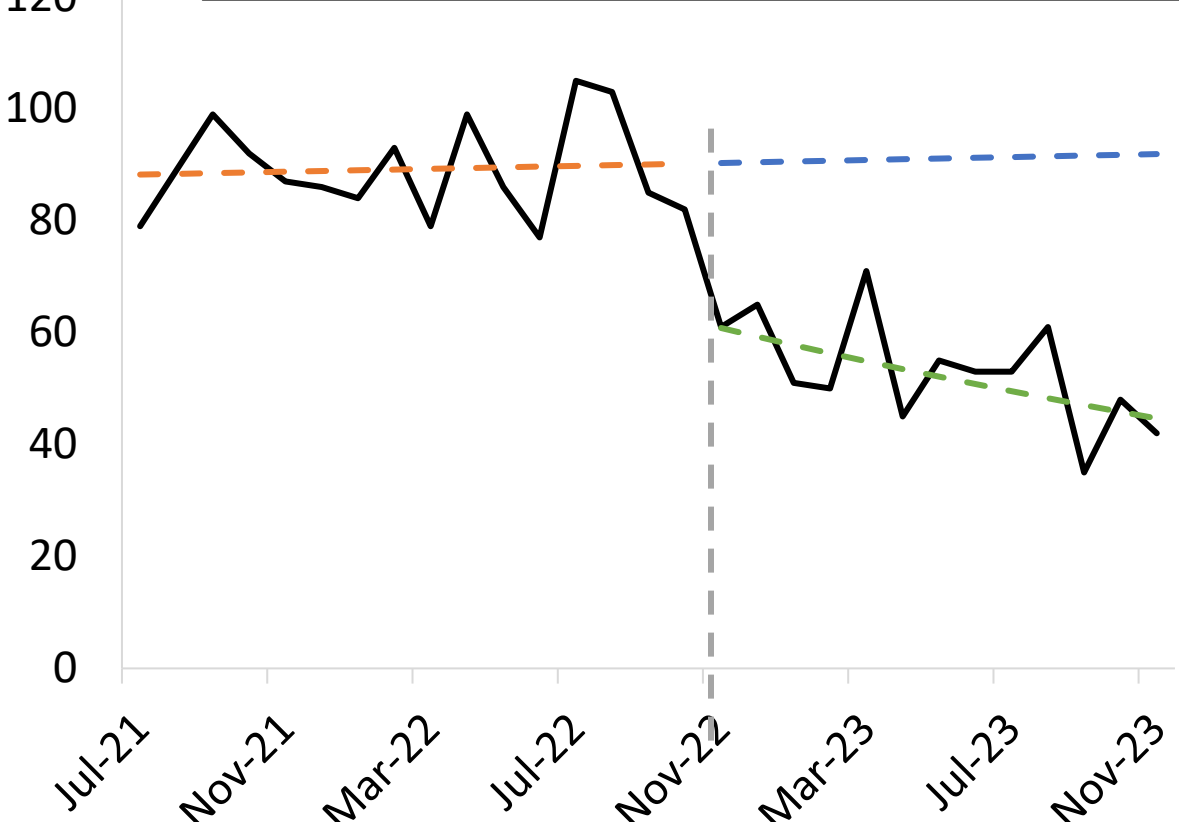
*Emotionally...that confidence [due to doxy-PEP] counts for a lot in terms of my mood, and my positivity, and my... sex positivity...before, there would be this kind of cloud of shame come over [a sex act]. (Age 44, HIV-, Seattle)*

# Decline in **citywide** chlamydia and early syphilis cases in MSM in SF after release of doxy-PEP guidelines

In Nov 2023, observed **chlamydia** cases were **50%** (95% CI 38%-59%) lower than model forecasts

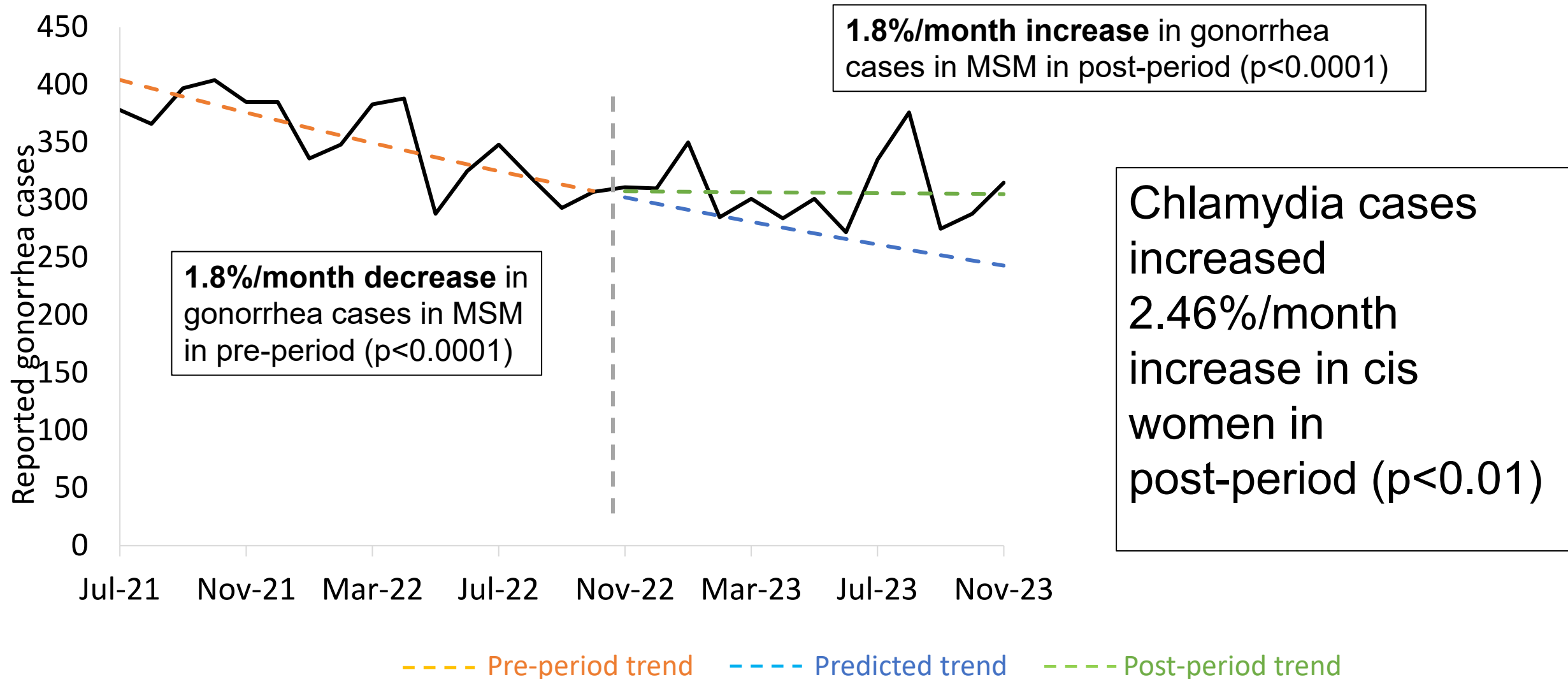


In Nov 2023, observed **syphilis** cases were **51%** (95% CI 43%-58%) lower than model forecasts



----- Pre-period trend    ----- Predicted trend    ----- Post-period trend

# No decline in **citywide** gonorrhea cases in MSM, and continued increases in chlamydia in cis women in SF after release of doxy-PEP guidelines



# Conclusions

- SFDPH moved quickly to translate evidence from a research study into services for our community
- Remarkable citywide collaboration and our engaged community facilitated early adoption of this new tool
- Early evidence of a population-level impact of doxy-PEP on chlamydia and syphilis rates, but not gonorrhea
  - Longer follow-up and to replicate findings in other jurisdictions
  - Information about antimicrobial resistance
- Providers should support their patients in assessing their need for, interest in, and use of doxy-PEP
- Guidelines for doxy-PEP can and should evolve as evidence emerges, informed by community input

# Thank You!

## SF City Clinic patients and study participants

- Maddie Sankaran
- Dave Glidden
- Oliver Bacon
- Trang Nguyen
- Bob Kohn
- Franco Chevalier
- Judith Sansone
- Montica Levy
- Christopher Ruiz
- Alyson Decker
- Julia Janssen
- Erin Antunez
- Rebecca Shaw
- Meya Harris
- Jennifer Lopez
- Jasmine Hawkins
- Frank Strona
- Ricardo Beato
- Romeo de la Roca
- Thu Tran
- Gina Limon
- Shornora Miller
- Yong Chun Huang
- Shai Wallace
- Terry Marcotte
- Bettemie Prins
- Clara Shayevich
- Edward Liu
- Elizabeth Faber
- Sally Grant
- Tony Sayegh
- Tae-Wol Stanley
- Yvonne Piper
- Sari Bushman
- Ameera Snell
- Tamar Besson
- Nyisha Underwood
- Thomas Knoble
- Hanna Hjord
- Oscar Macias
- Nikole Trainor
- Rio Bauce
- Frank Strona
- Ricardo Beato
- Alejandro Vigil
- Grecia Sambrano
- Meyana Tillman
- Francisco Garcia
- Johnson Mao
- Tova Israel
- Wendy Ho
- Antonia Guatemala
- Jonathan Carlson
- Amy Kwan
- Rho\* Torres
- Anthony Taylor
- Crecy James
- Pearl Aine
- Wanda Anderson
- Veronica Aburto
- Adrian Vargas
- Joey Sweazey
- Ki-Shawna Hampton
- Ryanne Brown
- Rigoberto Mendez
- Alison Cohee
- Melody Nasser
- Dorien Cimmiyotti
- Nikolas Alves da Costa E Silva
- Annie Luetkemeyer
- Connie Celum
- Susan Buchbinder
- Chase Cannon
- Julie Dombrowski
- Hyman Scott
- Jorge Roman
- Jason Bena
- Matt Spinelli
- Thiago Torres
- Courtney Liebi
- Brad Hare
- Jonathan Volk
- SF Getting to Zero
- DoxyPEP study team
- Susan Philip
- Grant Colfax







## DoxyPEP at a Boston Community Health Center and National Survey Data

---

Kenneth H. Mayer, MD

CDC-HRSA HIV/AIDS Advisory Committee

April 10<sup>th</sup>, 2024

[thefenwayinstitute.org](http://thefenwayinstitute.org)



# DoxyPEP: Fenway Health



Based in downtown Boston, Massachusetts  
Federally Qualified Healthcare Center, Founded 1971

**Mission** To enhance the wellbeing of the LGBTQIA+ community as well as people in our neighborhoods and beyond through access to the highest quality health care, education, research, and advocacy

Serving  $\approx$  35,000 patients, with approximately 2,200 PLHIV and 3,500 on PrEP.

## The Fenway Institute

- Research, Education, Policy
- Involved in NIH and other funded HIV Prevention Research



# Guidelines in the US

## Local / state health departments

- First to put out recommendations after the large trials were announced



POPULATION HEALTH DIVISION  
SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

### Recommendations

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  $\geq 1$  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.

## NEW YORK STATE DEPARTMENT OF HEALTH AIDS INSTITUTE

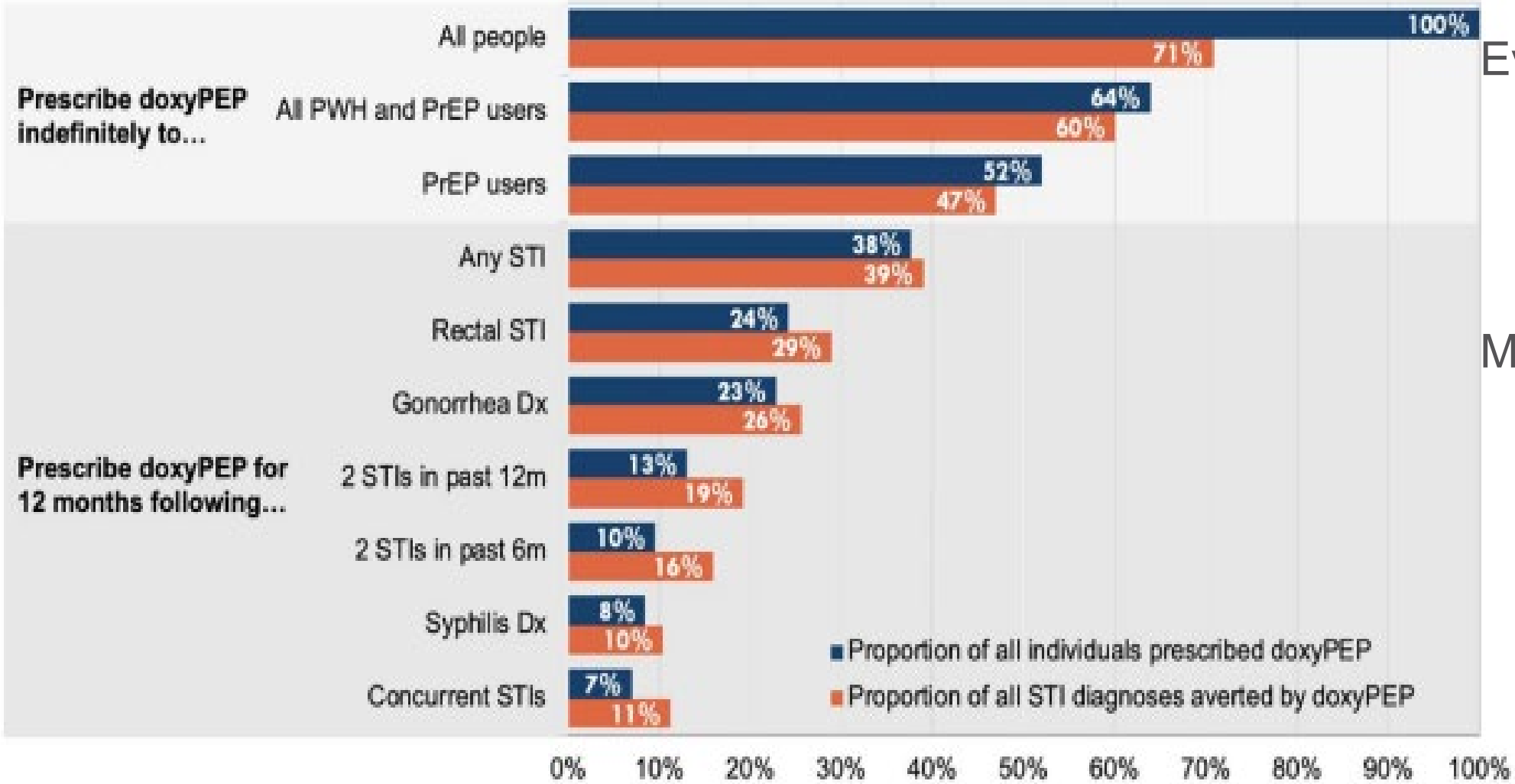
### ALL RECOMMENDATIONS: DOXYCYCLINE POST-EXPOSURE PROPHYLAXIS TO PREVENT BACTERIAL SEXUALLY TRANSMITTED INFECTIONS

#### Biomedical Prevention of STIs

- Clinicians should offer doxy-PEP to cisgender men and transgender women who are taking HIV PrEP or receiving HIV care and 1) engage in condomless sex with partner(s) assigned male sex at birth and 2) have had a bacterial STI diagnosed within the past year and are at ongoing risk of STI exposure. (A1)
- Clinicians should offer doxy-PEP to cisgender men and transgender women who are *not* taking HIV PrEP or receiving HIV care and 1) engage in condomless sex with partner(s) assigned male sex at birth and 2) have had a bacterial STI diagnosed within the past year and are at ongoing risk of STI exposure. (A2†)
- Clinicians should engage in shared decision-making with cisgender men who 1) engage in condomless sex with multiple partners assigned female sex at birth and 2) have had a bacterial STI diagnosed within the past year, offering doxy-PEP on a case-by-case basis. (B3)
- When prescribing doxy-PEP, clinicians should use the dosing regimen of oral doxycycline 200 mg taken ideally within 24 to 72 hours of condomless sex (A1) and counsel patients (A\*) on the key points for patient education outlined in [Table 1: Considerations for Doxy-PEP Implementation](#).
- For individuals taking doxy-PEP, clinicians should screen for HIV, chlamydia, gonorrhea, and syphilis at least every 3 months. (A1)
- Clinicians should offer HIV PrEP to individuals who do not have HIV and are initiating or using doxy-PEP. (A\*)
- Clinicians should [offer HIV treatment](#) to individuals with HIV who are not on antiretroviral therapy and are initiating or using doxy-PEP. (A1)

**Abbreviations:** doxy-PEP, doxycycline post-exposure prophylaxis; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection.

# “Focused” Identification Of Doxy-PEP Candidates



Evaluation of potential impact of hypothetical doxy-PEP prescribing strategies

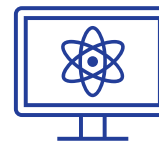
Most **efficient** prescribing strategies are based on STI history rather than HIV status or PrEP use

$$\text{Efficiency} = \frac{\% \text{ of STIs prevented}}{\% \text{ of individuals prescribed}}$$

# DoxyPEP: Fenway Health



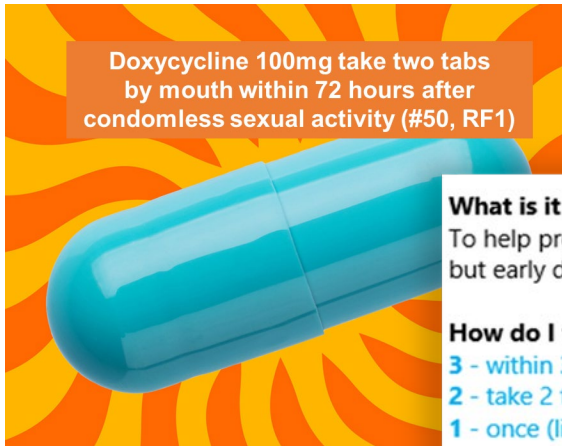
- Assign Male At Birth,  $\geq 18$ yo
- *Plus one of the following* -
  - A diagnosis of a bacterial STI in the last 12 months
  - PrEP Use,  $\geq 2$  sexual partners with condomless oral/anal sex
  - PLWH,  $\geq 2$  sexual partners with condomless oral/anal sex
  
- Shared Decision Making



DATA

IMPLEMENTATION

# DoxyPEP: Fenway Health



Doxycycline 100mg take two tabs by mouth within 72 hours after condomless sexual activity (#50, RF1)

## What is it for?

To help prevent getting chlamydia, syphilis and gonorrhea. It is not 100% protective - but early data suggests it can decrease numbers by 60%!

## How do I take it? "3-2-1"

3 - within 3 days or 72 hours

2 - take 2 tabs (or 200mg)

1 - once (limit to 1 time in one day)

- Take Doxycycline 100mg x 2 tabs (200mg together) once within 72 hours of possible exposure / risk - such as condomless oral/anal sex. It is better to take it within the first 24 hours.

- Do not take more than 200mg in one day. It is safe to take daily.

- Take with 8 oz of water and food if possible to help decrease any side-effects

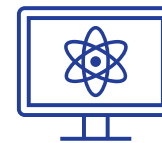
## Other important things to consider:

- We are still learning about the effects of DoxyPEP on "good" bacteria of the gut, changes to the bacteria that live on our skin (for example staph), and possible changes in resistance to STIs such as gonorrhea.
- Although doxycycline has been used for decades, there has been no resistance to doxycycline in chlamydia or syphilis.
- If you are having symptoms of an STI, come in to get tested and treated - otherwise continue your routine testing every 3 months.
- Doxycycline is not advised for persons that are pregnant/breastfeeding.

*We may reach out to you through MyChart at some point in the next few months to see how your experience with DoxyPEP has been going. This helps us to learn, make changes, and help others.*



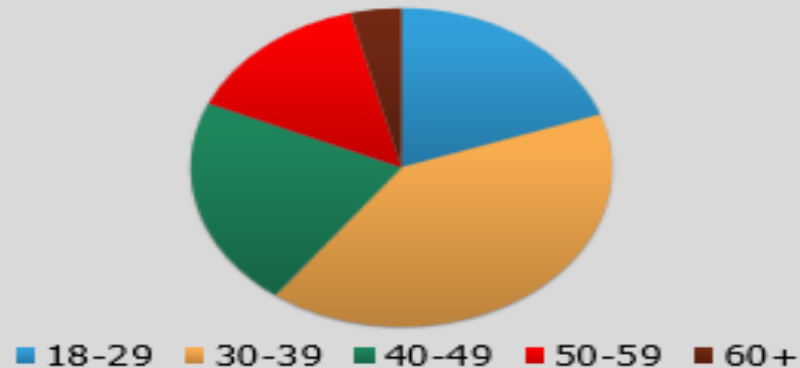
DATA



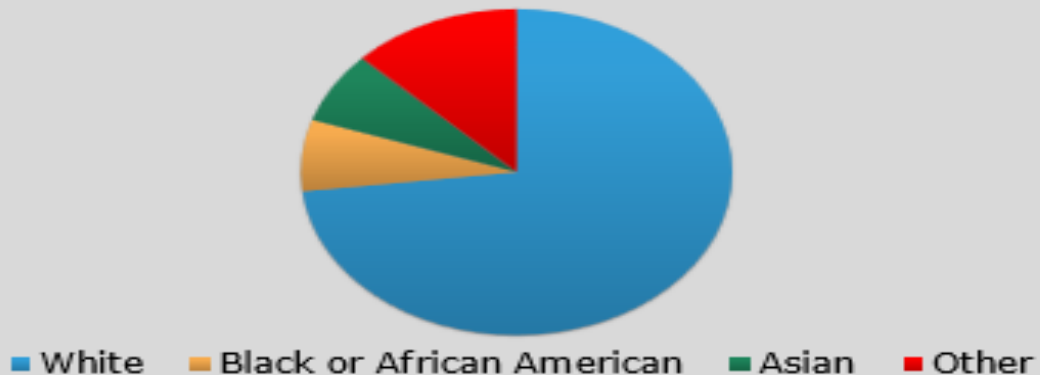
IMPLEMENTATION

# DoxyPEP: Fenway Health

### Patients prescribed DoxyPEP at Fenway Health, by Age

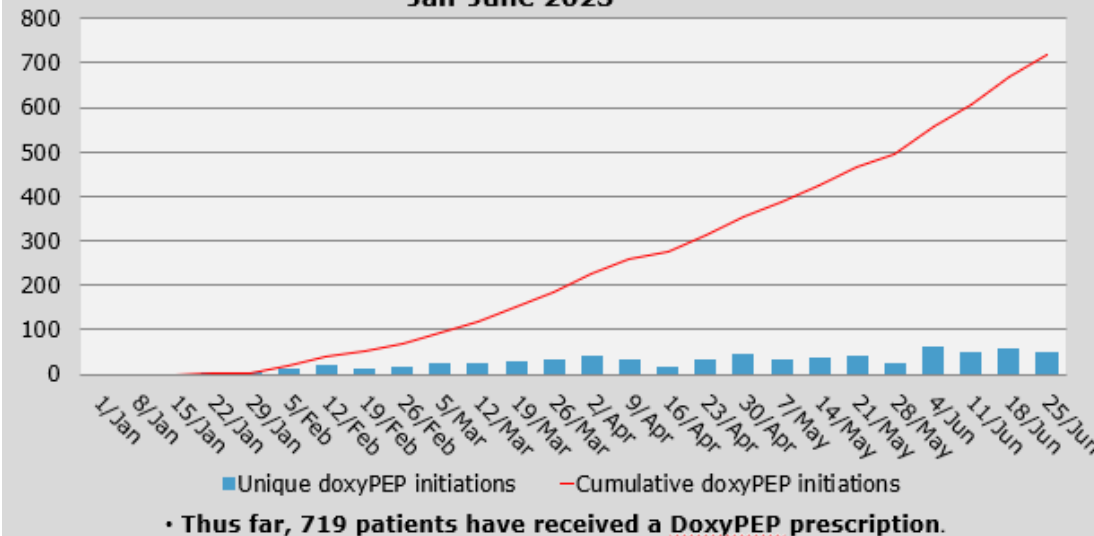


### Patients prescribed DoxyPEP at Fenway Health, by Race



Hispanic, Latinx – 15.6%  
PrEP user (at end of follow-up) – 73.9%  
Living with HIV (at end of follow-up) – 8.8%

### Cumulative DoxyPEP initiations at Fenway Health, Jan-June 2023



- By the end of 2023, 1712 pts received doxyPEP prescriptions
- STI testing frequency increased, while percent positive tests for GC and CT were decreased, c/w clinic level impact



# Early Adopters: Implementation of DoxyPEP in a Boston Health Center

(Mayer et al, CROI, 2024)

Comparison of DoxyPEP users with other men screened for a bacterial STI (bSTI) at Fenway Health (N=4,927; >1100 doxyPEP users, Fall 2023)

- DoxyPEP uptake:
- 24.1% of patients with an active PrEP prescription
  - 4.8% of PLHIV
  - 13.7% of those screened for a bSTI in 2022
  - 24.7% of those diagnosed with a bSTI in 2022

Variable	DoxyPEP Users	DoxyPEP Non-Users	O.R.	95% C.I.
<b>PrEP Users</b>	73.8%	39.9%	4.25	3.67-4.93
<b>Private Insurance</b>	85.4%	71.3%	2.37	1.96-2.81
<b>bSTI dx in 2022</b>	31.3%	15.0%	1.67	1.42-1.98
<b>PLHIV</b>	8.6%	18.1%	0.42	0.34-0.53



# National Survey of Antibiotic Prophylaxis (Trager et al, CROI 2024)



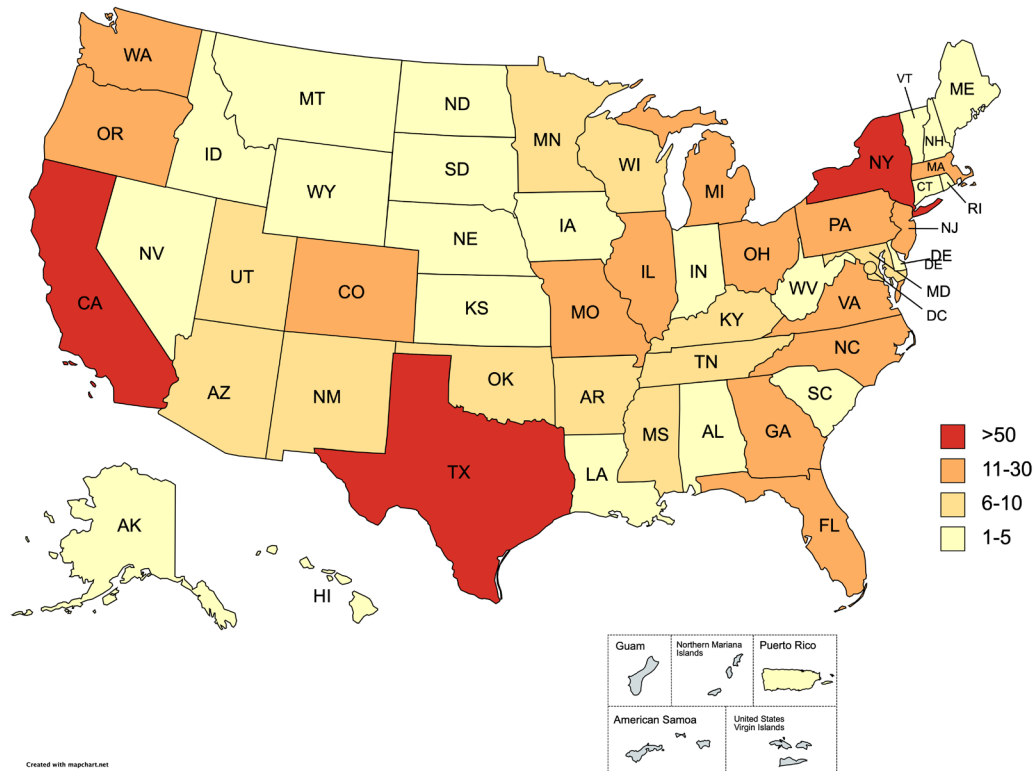
903 respondents recruited on MSM sex networking sites, Sept 2023

## Demographics

Mean age = 42 years

866 (96%) were assigned male sex at birth  
Of which 96% identified as gay or bisexual male

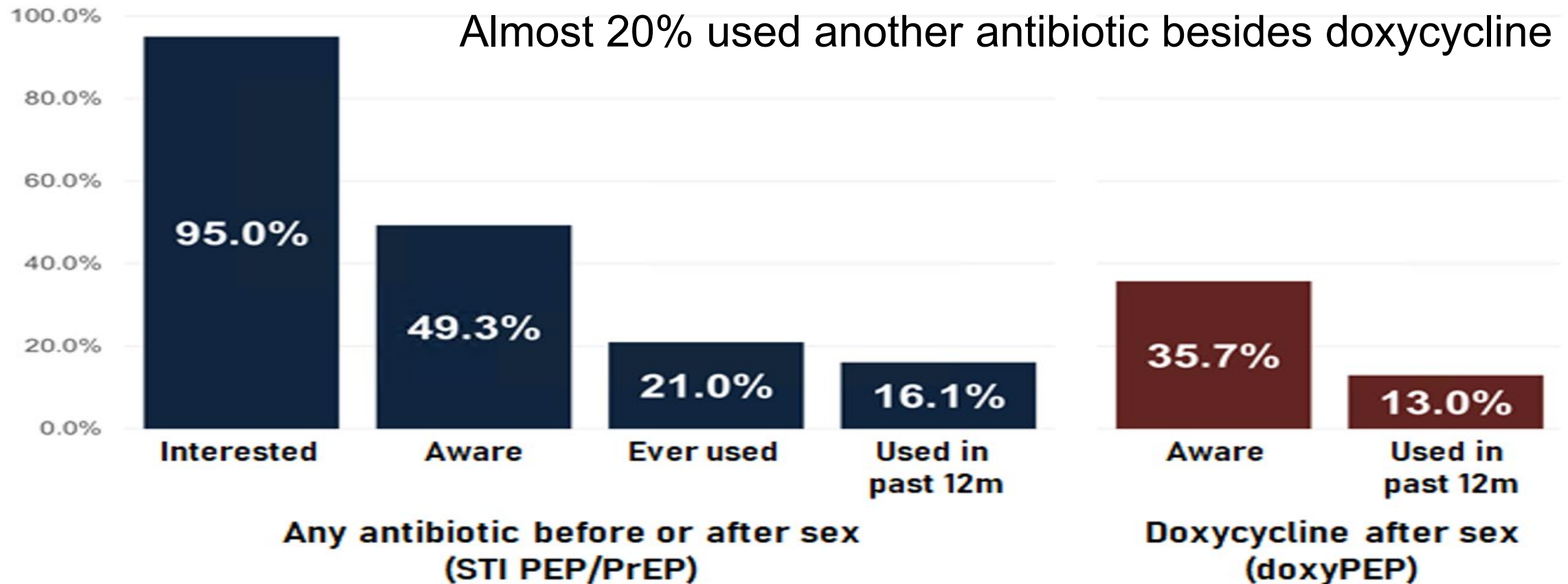
19% living with HIV  
42% using HIV PrEP



Created with mapchart.net

# US Survey Of MSM STI Antibiotic Prophylaxis (Traeger Et Al)

## 903 MSM Recruited Via Sex Networking Apps

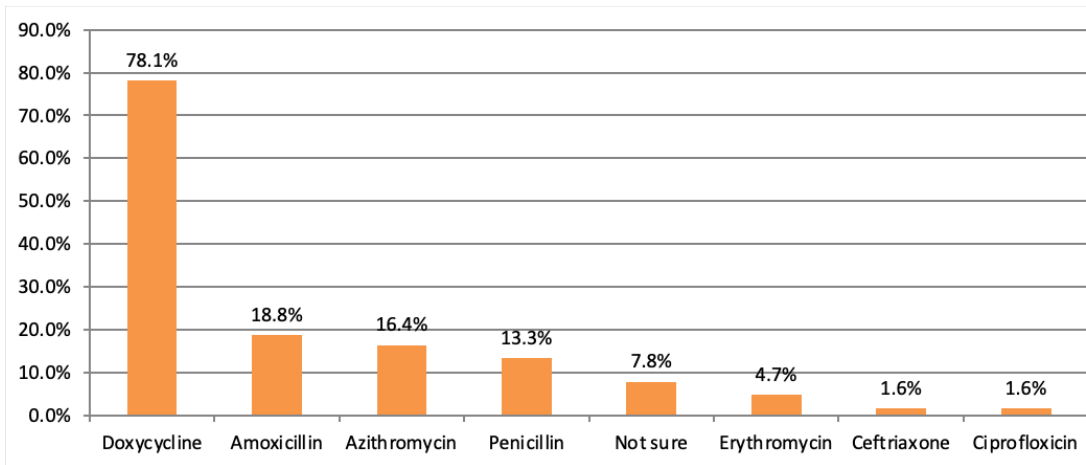


# Preliminary results (Traeger et al)

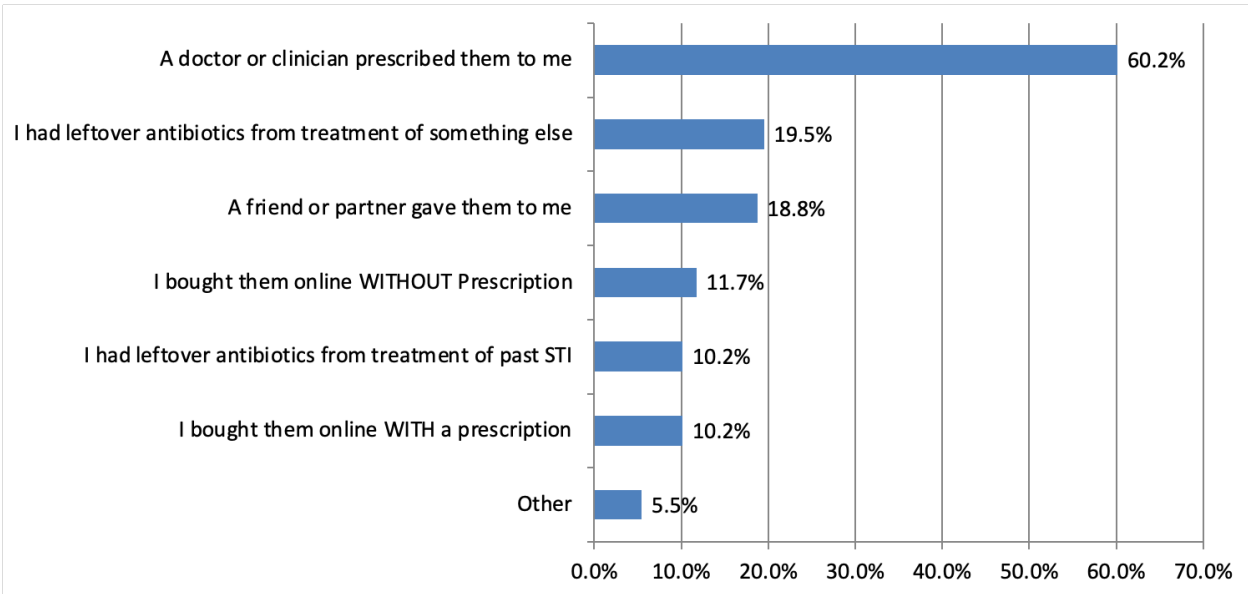
45% had used antibiotics before sex  
72% had used it after sex

With casual sex partner in the past 12m:  
47% used it some of the time  
32% used it most of the time  
21% used it all of the time

For DoxyPEP users  
24% had used a dosage other than a single 200mg dose (recommended)



When using antibiotics around the time of sex to prevent getting an STI, which antibiotics have you used?



Where did you get the antibiotics?

# Conclusions

- DoxyPEP scale up was feasible and highly acceptable at a Boston community health center
- Attention to ensuring equity remains important
- Early suggestions that doxyPEP roll-out may be having a local population impact need further study
- National data suggest high levels of interest and some possible misuse of antibiotic prophylaxis
- Community and provider education and clear guidelines are important in order to enhance optimal uptake.

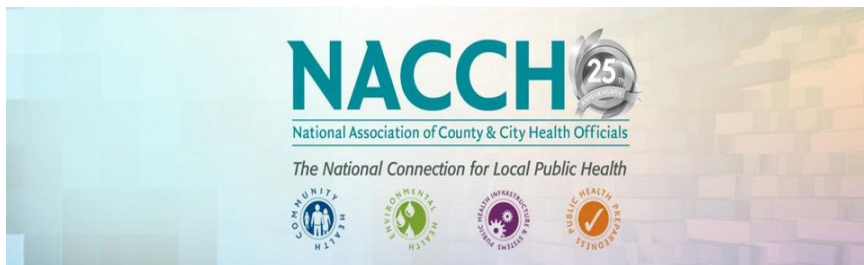
**FI** THE FENWAY INSTITUTE  
FENWAY **FI** HEALTH



# Thank You

Taimur Khan, Doug Krakower, Jess Kraft, Julia Marcus, Sy Gitin, Michael Traeger, NCSD and NACCHO (Rebekah Horowitz and Lucy Slater)

.....



[thefenwayinstitute.org](http://thefenwayinstitute.org)

