

# Stronger Together: Exploring the Cross-Cutting Benefits of HIV and STI Prevention

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# Speaker Disclosures

Speaker: Dr. Anu Hazra

Disclosures:

- Unrestricted research grant, Gilead Sciences
- Advisory Board, Gilead Sciences, ViiV Healthcare
- This presentation will include discussion of pharmaceuticals or devices that have not been approved by the FDA.
- “Off-label” use of HIV Pre-Exposure Prophylaxis (PrEP)

# Learning Objectives

- Describe the syndemic of HIV and STI
- Explore how novel STI prevention strategies like doxyPEP can be integrated to HIV prevention
- Recognize the challenges with doxyPEP implementation and how we can avoid the historical missteps of HIV PrEP

THE  
**STATE OF STIs**  
IN THE  
**UNITED STATES,**  
**2022**

**CDC's 2022 STI Surveillance  
Report underscores that STIs  
must be a public health  
priority**



**1.6 million**  
CASES OF CHLAMYDIA  
6.2% decrease since 2018



**648,056**  
CASES OF GONORRHEA  
11% increase since 2018



**207,255**  
CASES OF SYPHILIS  
80% increase since 2018

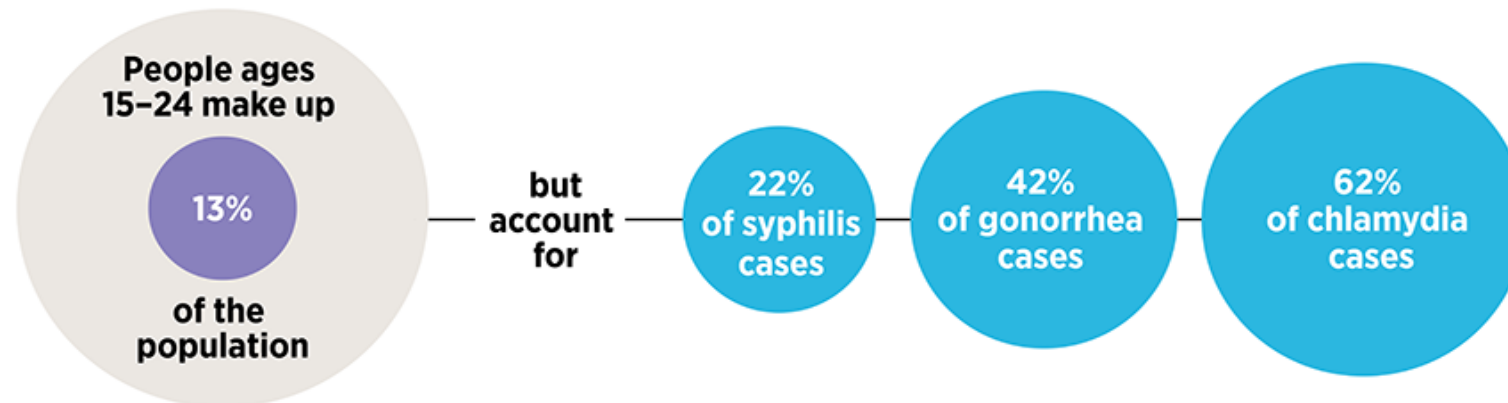


**3,755**  
CASES OF SYPHILIS  
AMONG NEWBORNS  
183% increase since 2018

LEARN MORE AT: [www.cdc.gov/std/](http://www.cdc.gov/std/)

# STATE OF STIS IN THE UNITED STATES

- 1 in 5 people in the United States had an STI in 2018 on any given day.
- Report case rates chlamydia, gonorrhea, and syphilis have been increasing over the last two decades.
- Although diagnosed STI rates have increased across all populations in the United States, marginalized groups—youth, women, lesbian, gay, bisexual, transgender, and queer (LGBTQ+) people, and Black, Latino/x, American Indian/Alaska



Centers for Disease Control and Prevention and U.S. Census Bureau.

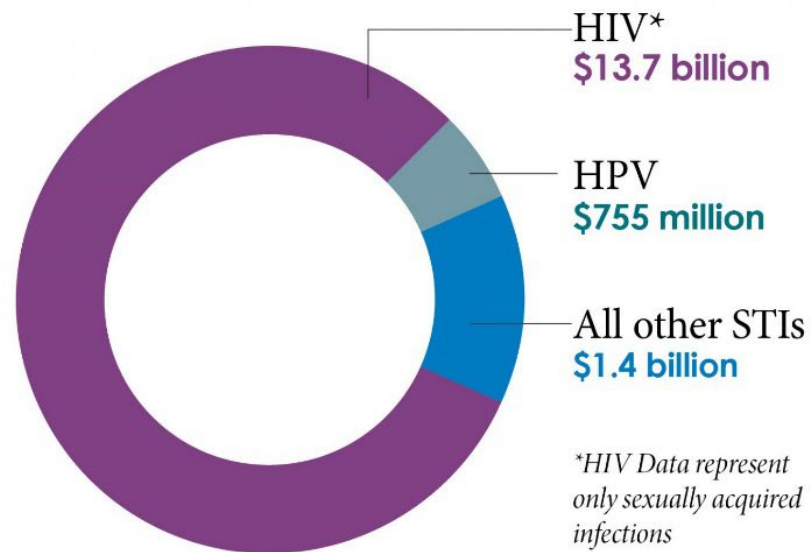


# MAGNITUDE OF THE PROBLEM

- Medical expenditures associated with STIs in the US are approaching \$16 billion per year
- Long-term effects of STIs include infertility, miscarriage or newborn death, and increased risk of HIV infection.
- CDC estimated that incident STIs imposed more than \$2 Billion in lifetime direct medical costs in the United States in 2018.

## STIs COST THE U.S. HEALTHCARE SYSTEM BILLIONS EACH YEAR

In 2018, new infections totaled nearly \$16 billion in direct lifetime medical costs



**\$** **CHLAMYDIA, GONORRHEA, and SYPHILIS** combined accounted for **\$1.1 billion** in direct medical costs  
*Care for young people (ages 15-24) accounted for about 60% of these costs*

**75%** of all STI-related direct lifetime medical costs (not including HIV care)  
*Care for women represented nearly*



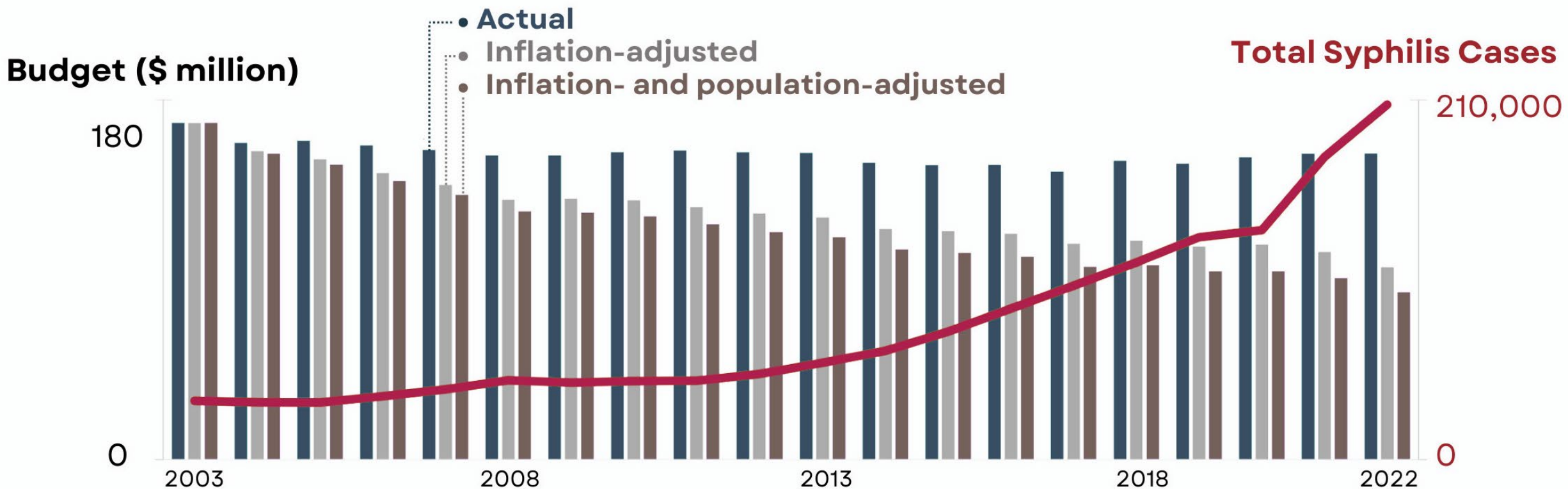
For more information visit [www.cdc.gov/nchstp/newsroom](http://www.cdc.gov/nchstp/newsroom)

<https://www.cdc.gov/nchstp-newsroom/resources/std.html>

Centers for Disease Control and Prevention and U.S. Census Bureau.

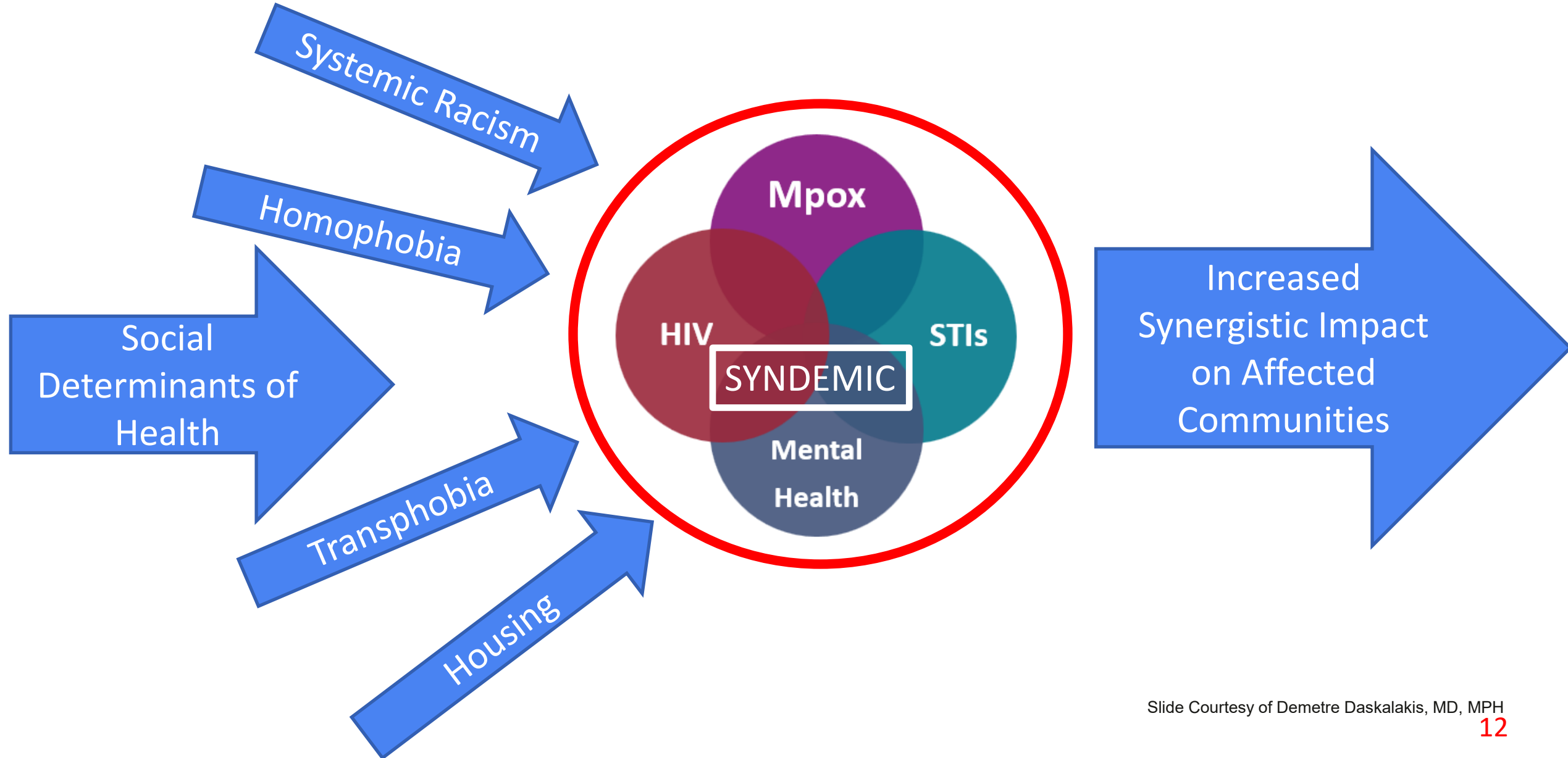
# Annual CDC STD Prevention Budget, FY 2003–FY 2022 and Total Syphilis Cases

*50% drop in per-capita purchasing power since 2003\**

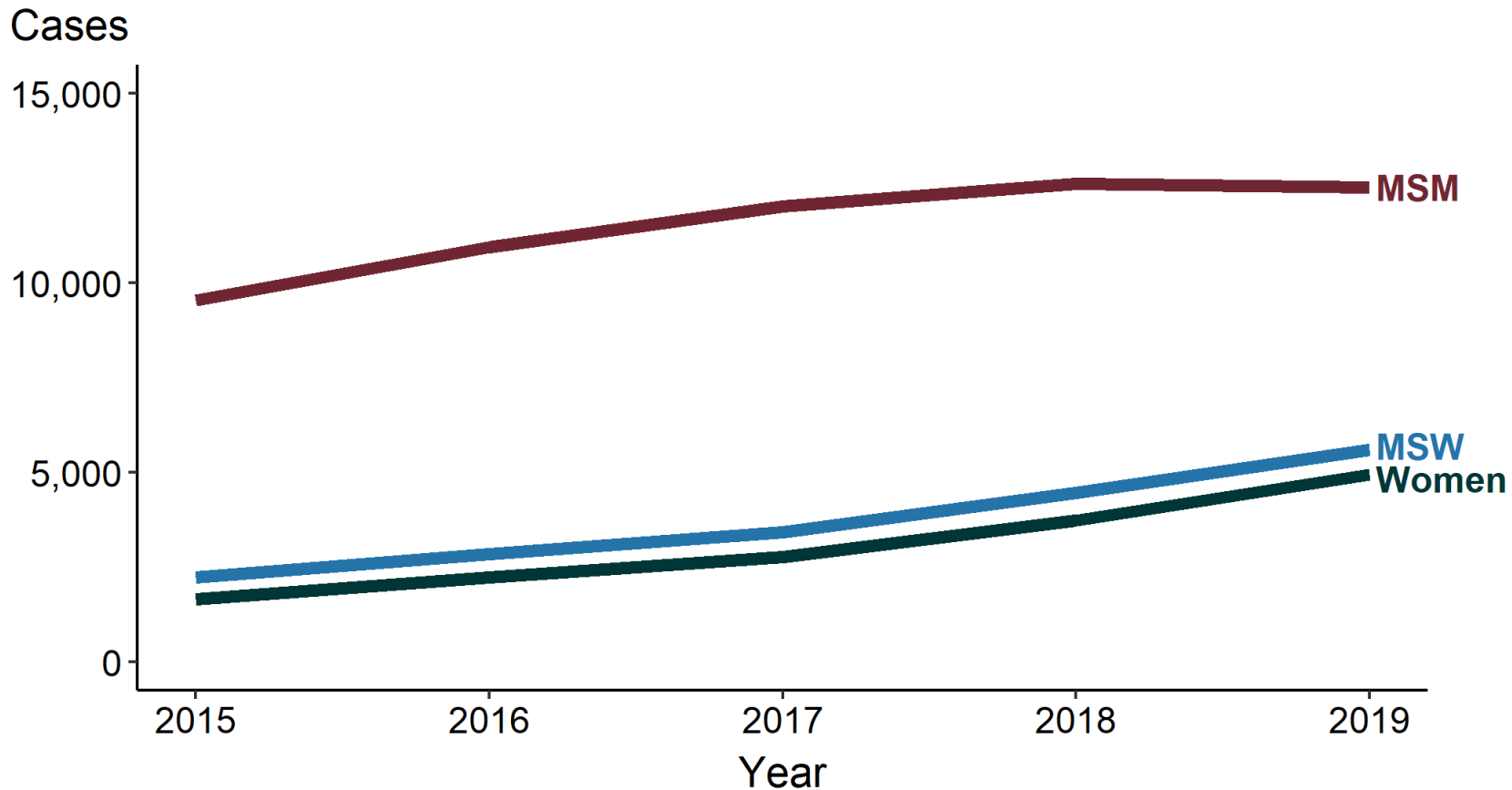


\*Inflation adjustment is to 2003 dollars. Funding years for the bars are USG fiscal years. Inflation adjustment used the “all items” component of the consumer price index (CPI). Population adjustment for a given year was calculated by dividing national population in 2003 by national population in the given year.

# Syndemic Problems Require Syndemic Solutions



# Primary and Secondary Syphilis — Reported Cases by Sex and Sex of Sex Partners, 31 States\*, 2015–2019

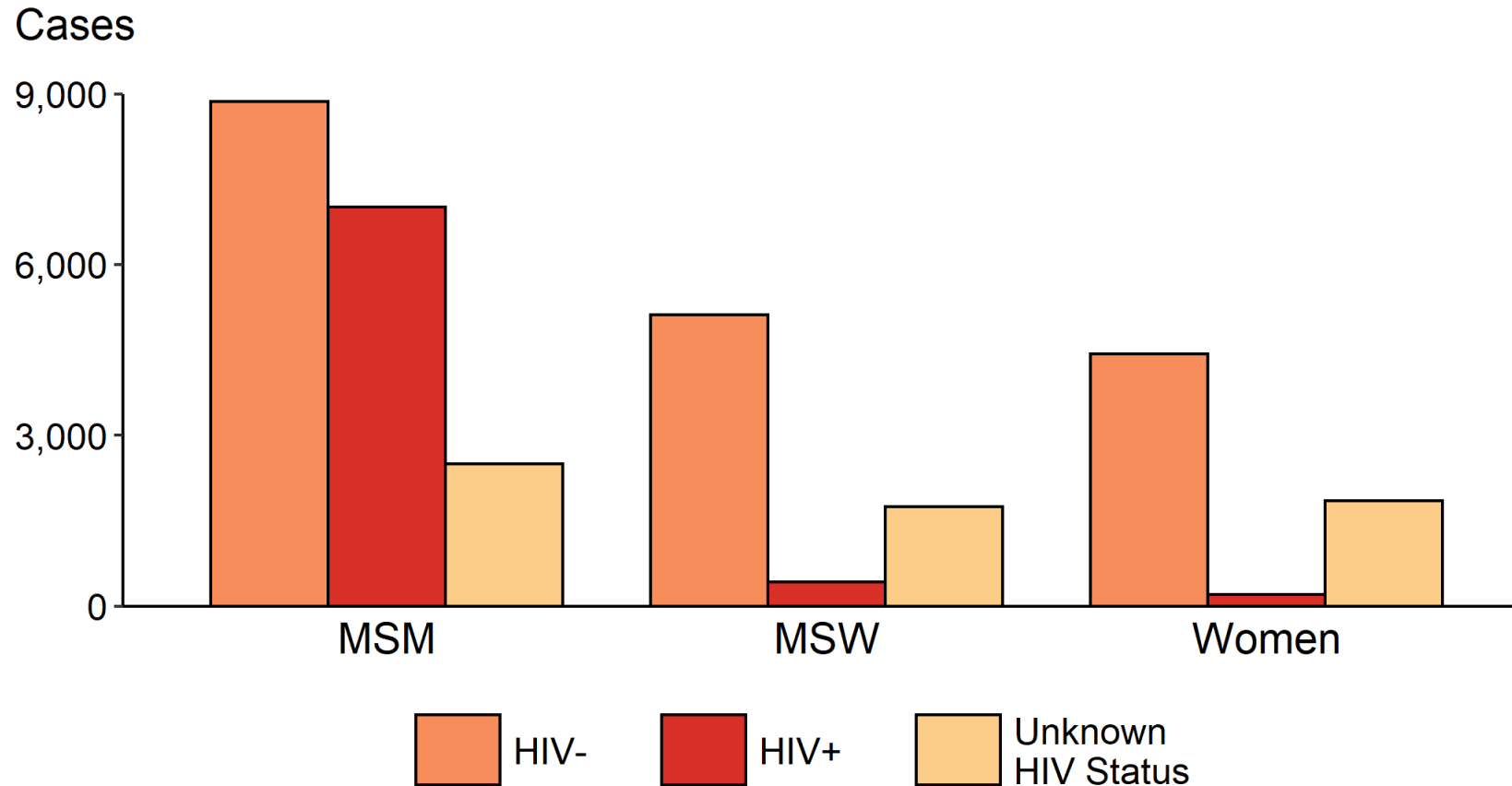


\*31 states were able to classify  $\geq 70\%$  of reported cases of primary and secondary syphilis among males as either MSM or MSW for each year during 2015–2019.

**ACRONYMS:** MSM = Gay, bisexual, and other men who have sex with men; MSW = Men who have sex with women only



# Primary and Secondary Syphilis — Reported Cases by Sex, Sex of Sex Partners, and HIV Status, United States, 2019



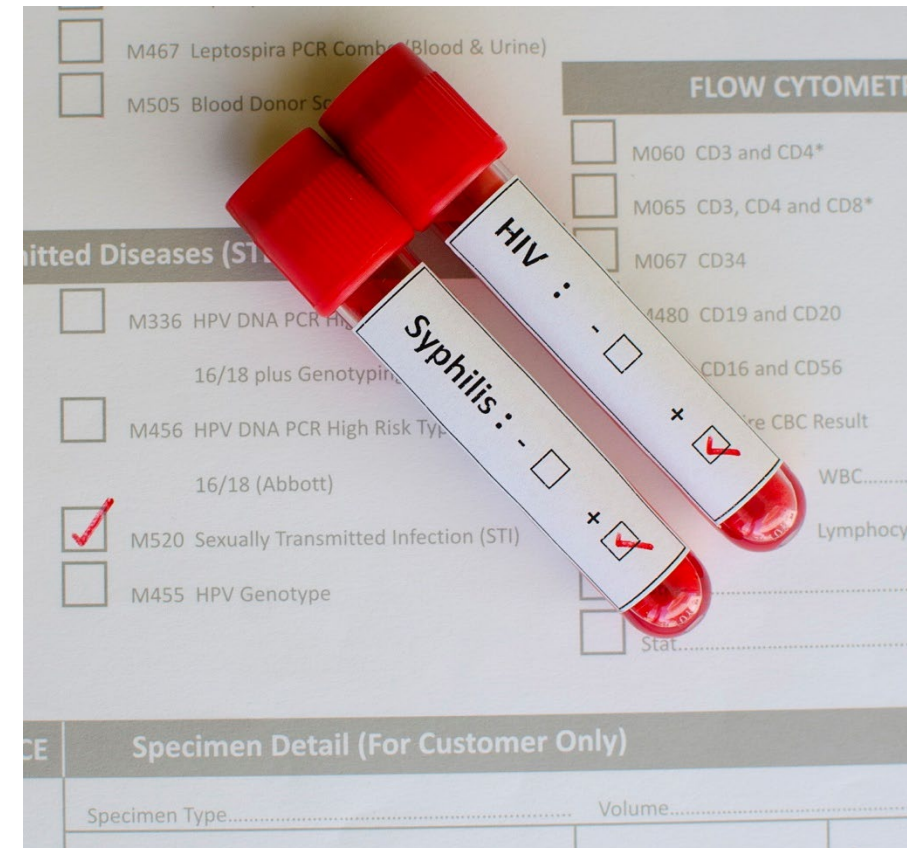
**ACRONYMS:** MSM = Gay, bisexual, and other men who have sex with men; MSW = Men who have sex with women only

Centers for Disease Control and Prevention and U.S. Census Bureau.



# SYPHILIS AND HIV

- Syphilis thought to facilitate HIV acquisition and transmission
  - HIV can be found on syphilitic lesions
  - Syphilis infection cause transient increase of HIV VL
- Epidemiological link between syphilis and HIV
  - High rates of HIV co-infection, particularly among MSM and TWSM
  - One study found median time to HIV diagnosis to be 1.6 years
- Increased morbidity in PWLH
  - Early neurosyphilis and ocular syphilis
  - Higher rates of treatment failure



Zetola NM, Klausner JD. Syphilis and HIV infection: an update. Clin Infect Dis. 2007 May 1;44(9):1222-8.

Pathela P et al. The high risk of an HIV diagnosis following a diagnosis of syphilis: a population-level analysis of New York City men. Clin Infect Dis. 2015 Jul 15;61(2):281-7.

# A Vicious Cycle: STDs *predict* future HIV

Rectal GC  
or CT



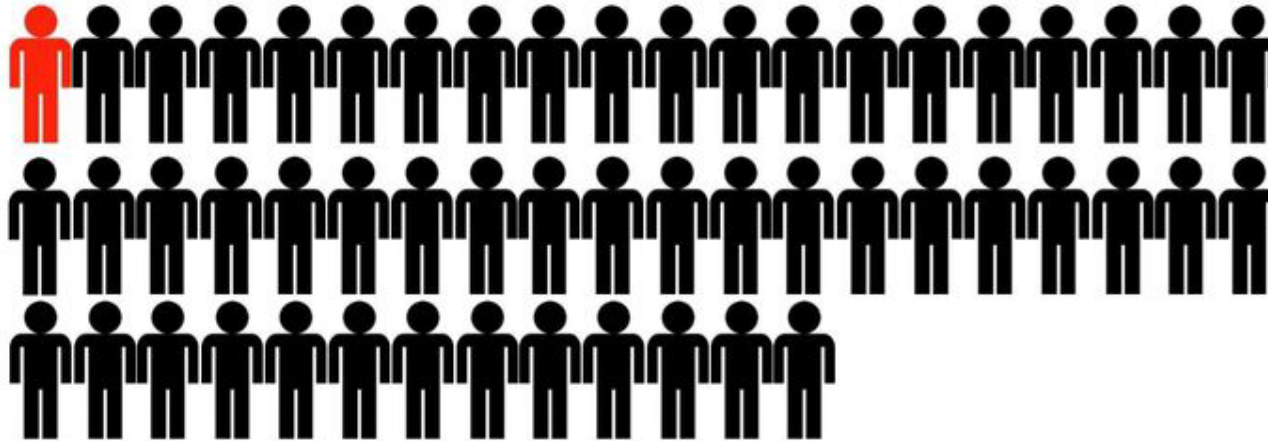
1 in 15 MSM were diagnosed with HIV within 1 year.\*

Primary or  
Secondary  
Syphilis



1 in 18 MSM were diagnosed with HIV within 1 year.\*\*

No rectal STD  
or syphilis  
infection



1 in 53 MSM were diagnosed with HIV within 1 year.\*

# DOXYCYCLINE

- Second-generation tetracycline antibiotic
- Widely available, inexpensive, and well-tolerated
- Broad spectrum of anti-microbial activity
- Used to treat multiple STIs
  - 1<sup>st</sup> line therapy for chlamydia trachomatis infections
  - Alternative therapy for P&S syphilis infections
  - No longer used to treat N.gonorrhoea due to tetracycline resistance
- **Teratogenic drug class**, contraindicated in pregnancy
  - Review by the Teratogen Information System (TERIS) concluded that therapeutic doses during pregnancy are unlikely to pose a substantial teratogenic risk
  - Data are insufficient to state that there is no risk





# DOXYCYCLINE PRE-EXPOSURE PROPHYLAXIS (DOXY PREP)



- Randomized controlled pilot study of MSM LWH
- Subjects (n=30) were block randomized
  - Doxycycline hyclate 100mg daily for 36 weeks
  - Incentive-based arm for remaining STD-free (in addition to compensation to enroll in study)
- 73% reduction in syphilis, gonorrhea, or chlamydia in those taking Doxy PrEP with no difference in reported sexual behaviors between the two groups.

Bolan RK, Beymer MR, Weiss RE, Flynn RP, Leibowitz AA, Klausner JD. Doxycycline Prophylaxis to Reduce Incident Syphilis among HIV-Infected Men who have Sex with Men who Continue to Engage in High Risk Sex: A Randomized, Controlled Pilot Study. *Sexually transmitted diseases*. 2015;42(2):98-103.

# DOXYCYCLINE POST-EXPOSURE PROPHYLAXIS (DOXY PEP)

- Open-label extension of the ANRS IPERGAY trial in France
- MSM and TWSM without HIV (n=232) were randomly assigned (1:1)
  - single oral dose of 200 mg doxycycline PEP within 24h after sex (max 3x/wk)
  - no prophylaxis
- Primary endpoint was the occurrence of a first STI (gonorrhoea, chlamydia, or syphilis) during the 10-month follow-up



# DOXY PEP



## Demographics (n=232)

- 95% white
- Average age of 38
- 86% employed; 92% reported some college
- Average 10 partners in past 8 weeks
- Average 10 sex actions in past 4 weeks
- 17% with STI at baseline visit
- Followed for median 8.7 months

# DOXY PEP



- Doxy PEP reduced the occurrence of a first episode of bacterial STI by 47%
  - no significant difference in reported sexual behaviors
- Reduction of chlamydia and syphilis infections by 70% and 73% respectively with 200mg Doxy PEP
- Rates of gonococcal infections between the two groups did not differ
  - No change in genotypic markers of tetracycline resistance
- No HIV seroconversions were observed

# DOXY PEP



- No difference between doxy PEP and no PEP arms for:
  - Number of sex acts in past 4 weeks
  - Number of sex partners in past 8 weeks
  - Condomless anal sex encounters
  
- Condom use with anal sex declined in both groups from 20% to 10%

# ADVERSE EFFECTS WITH DOXY PEP

	PEP (n=116)	No PEP (n=116)	p value
Any adverse events	106 (91%)	104 (90%)	0.65
Any serious adverse events	5 (4%)	10 (9%)	0.18
Any grade 3 or 4 events	4 (3%)	8 (9%)	0.24
Treatment discontinuation because of adverse events	8 (7%)	NA	..
Gastrointestinal adverse events	62 (53%)	47 (41%)	0.05
Drug-related gastrointestinal adverse events	29 (25%)	16 (14%)	0.03
Nausea or vomiting	10 (9%)	3 (3%)	..
Abdominal pain	14 (12%)	5 (4%)	..
Diarrhoea	6 (5%)	9 (8%)	..
Other gastrointestinal disorders	5 (4%)	1 (1%)	..
Confirmed laboratory events			
Elevated plasma creatinine			
All grades	15 (13%)	15 (13%)	1.00
Grade 2	3 (3%)	0 (0%)	..
Proteinuria grade 2 or worse	4 (3%)	5 (4%)	0.73
Glycosuria grade 2 or worse	1 (<1%)	1 (<1%)	1.00
Elevated ALT concentrations			
All grades	14 (12%)	20 (17%)	0.27
Grade 4	1 (<1%)	2 (2%)	1.00

Data are n (%). Only the first occurrence of adverse events per patient was reported. ALT=alanine aminotransferase. PEP=post-exposure prophylaxis (with doxycycline).

**Table 3: Adverse events according to study group**

- Participants used on average 6.8 pills of doxycycline a month
- Frequency of Grade 3 or 4 AE did not differ
- Higher rates of GI AEs in Doxy PEP group
- 8 patients (7%) discontinued doxycycline due to AEs

# GAUGING CURRENT INTEREST

- Survey of MSM and TWSM seen at STI Clinics in Toronto and Vancouver found:
  - 60.1% would be willing to use doxy PEP
  - 44.1% would be willing to use doxy PrEP
- Survey of Australian MSM found:
  - 52.7% would be very or slightly likely to use doxycycline to prevent syphilis
  - 75.8% felt very or slightly strongly that chemoprophylaxis would help reduce syphilis infections in their communities

Fusca L, Hull M, Ross P, et al. Exposure Prophylaxis Among Gay, Bisexual and Other Men Who Have Sex With Men in Vancouver and Toronto. *Sex Transm Dis*. 2020 Jan 17. Epub ahead of print

Wilson DP, Prestage GP, Gray RT, et al. Chemoprophylaxis is likely to be acceptable and could mitigate syphilis epidemics among populations of gay men. *Sex Transm Dis* 2011; 38:573–9

# GAUGING CURRENT INTEREST & USE

- Large multi-city sample of individuals using a gay social networking app
  - 84% of participants expressed interest in trying doxy PEP
  - **African-American and Hispanic/Latinx respondents had higher interest in doxycycline-PEP than White respondents**
- Prevalence of doxycycline PEP/PrEP use in Seattle
  - **9.3% reported already using doxycycline prophylaxis**
  - Willingness to take doxycycline prophylaxis was more common among those with HIV (62%) or on PrEP (60%)

Spinelli MA, et al. High Interest in Doxycycline for Sexually Transmitted Infection Postexposure Prophylaxis in a Multicity Survey of Men Who Have Sex With Men Using a Social Networking Application. *Sex Transm Dis.* 2019;46(4):e32-e34.

Dombrowski JC. Doxycycline Prophylaxis Use among Cisgender Men and Transgender Persons who have Sex with Men in Seattle. *CDC STD Prevention Conference 2020.*



# TARGET POPULATION FOR DOXY PEP/PREP

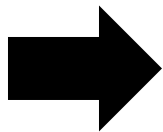
- Large proportion of STIs occur among those with repeat infections
- In Massachusetts between 2014-2016
  - 0.2% of the general population acquired  $\geq 1$  repeat STI diagnoses
  - Accounted for 27.7% of all STIs during the same period
- “Core” disease transmitters disproportionately effected by STI morbidity
- Novel STI prevention efforts need to start with this population

# W DOXYPEP

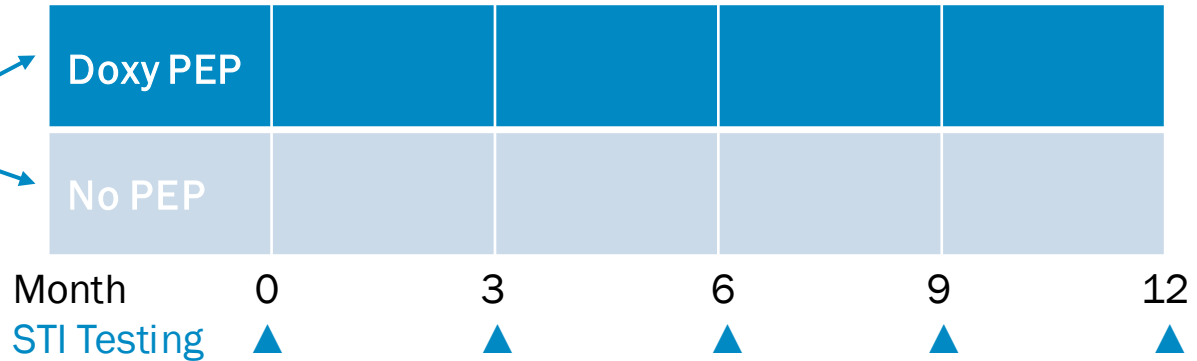
MSM & TGW  
HIV +  
(n=390,  
planned)

&

MSM & TGW  
On HIV PrEP  
(n=390,  
planned)



Open label doxycycline 200 mg after condomless sex



## Inclusion Criteria:

- Male sex at birth
- >1 STI in previous 12 months
- Condomless sex with  $\geq 1$  male partner in past 12 months

## Population:

- PrEP (n=327); HIV+ (n=174)
- Non-white - 33%, Hispanic -30%
- Median # sexual partners in previous 3 months -9
- Substance use in past 3 months -59%

## Adherence:

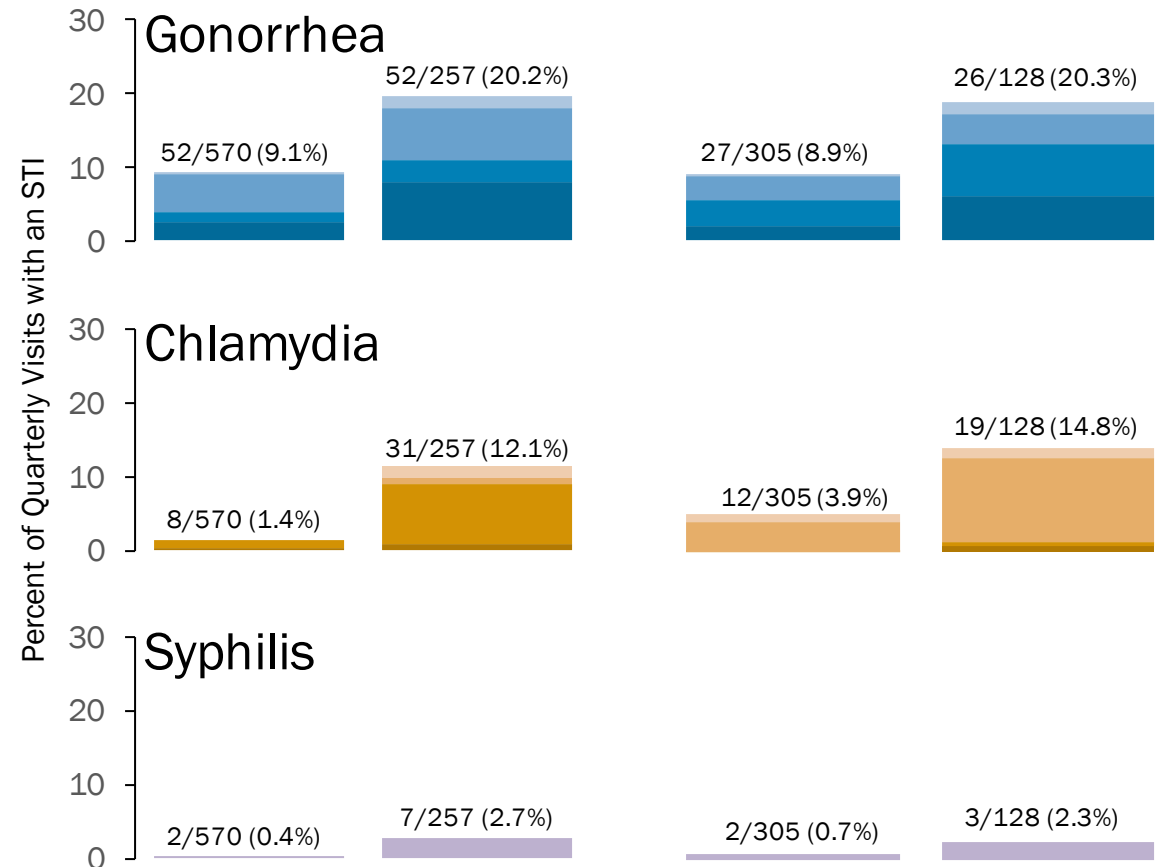
- 87% of condomless sex acts covered
- Median 7 sex acts per month
- 16% took  $\geq 20$  doses/month
- 30% took 10-20 doses/month

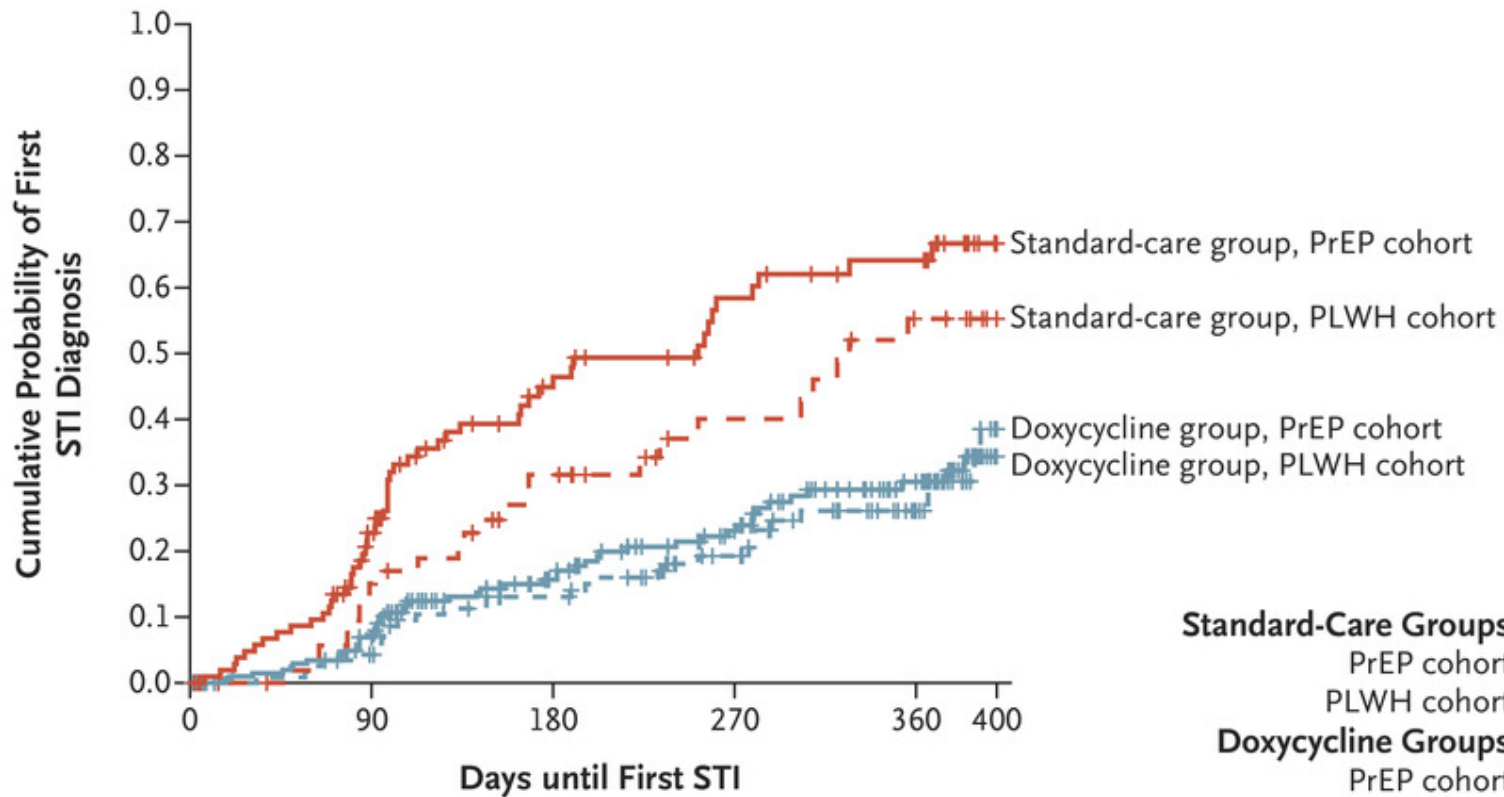
**Primary Outcome:** Risk reduction in STI Incidence per quarter - 0.35 (0.27 – 0.46),  $p < 0.0001$

Reduction in each STI per quarter risk reduction (95% CI)		
	PrEP	PLWH
<b>GC</b>	0.45 (0.32 – 0.65) $p < 0.0001$	0.43 (0.26 – 0.71) $p = 0.001$
<b>CT</b>	0.12 (0.05 – 0.225) $p < 0.0001$	0.26 (0.12 – 0.57) $p < 0.0007$
<b>Syphilis</b>	0.13 (0.03 – 0.59) $p = 0.0084$	0.23 (0.04 – 1.29) $p = 0.095$

### PrEP cohort

### PLWH cohort





**No. of Events/  
No. of Participants**

**Standard-Care Groups**

PrEP cohort 53/107  
PLWH cohort 24/55

**Doxycycline Groups**

PrEP cohort 51/220  
PLWH cohort 30/119

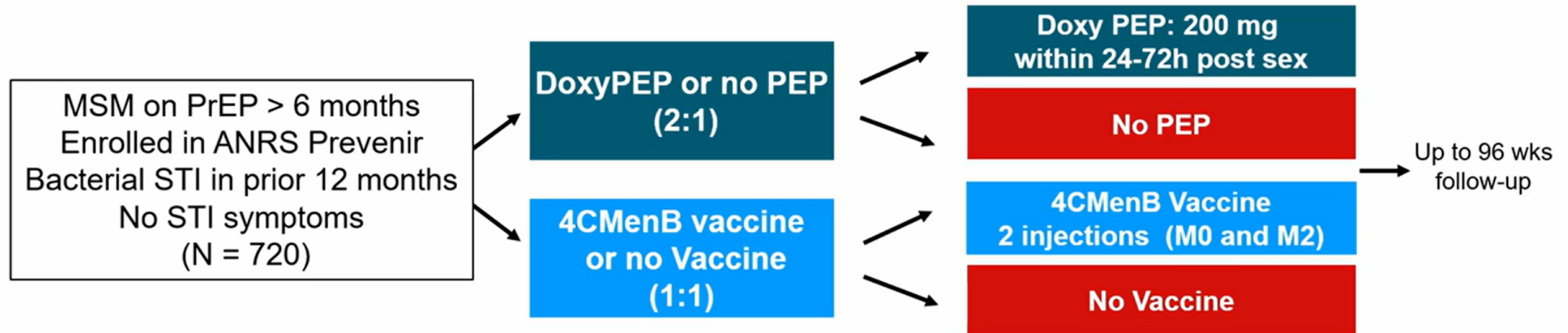
Hazard ratio for PrEP cohort,  
0.34 (95% CI, 0.23–0.51)  
Hazard ratio for PLWH cohort,  
0.48 (95% CI, 0.28–0.83)

**No. at Risk**

Standard-care groups					
PrEP cohort	107	72	37	23	17
PLWH cohort	55	45	30	20	13
Doxycycline groups					
PrEP cohort	220	179	122	93	57
PLWH cohort	119	111	91	64	36

# Study Design

- Multicenter, 2 x 2 factorial randomized, open-label, superiority, phase III trial (NCT04597424)



- Primary efficacy end-points: impact of DoxyPEP on time to a first episode of syphilis or chlamydia and impact of the 4CMenB vaccine on time to a first episode of *N. gonorrhoeae* infection.
- Sample size: based on vaccine effectiveness assuming no impact of Doxy PEP on GC: 720 subjects needed for an HR: 0.70 (Estimated probability of a first GC episode over 18 months: 52%, 18% lost to FU).
- Quaterly visits with PCR tests (Roche dual target Cobas<sup>o</sup>) for GC/CT/MG (3 sites) and serology for TP
- Doxycycline monohydrate purchased from Arrow and 4CMenB vaccine purchased from GSK

# DOXYVAC RESULTS - DOXYPEP

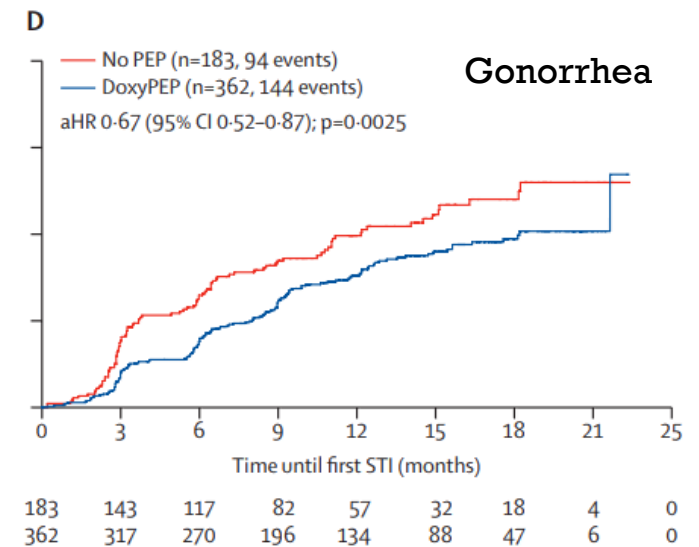
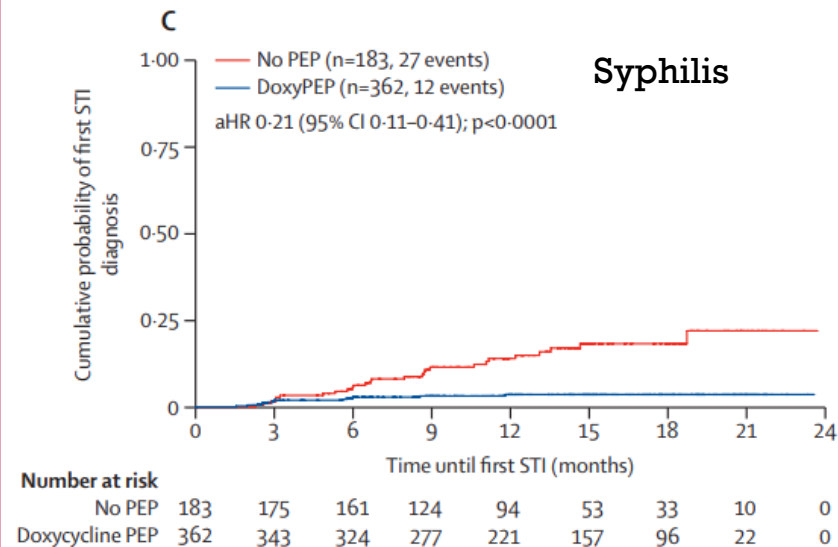
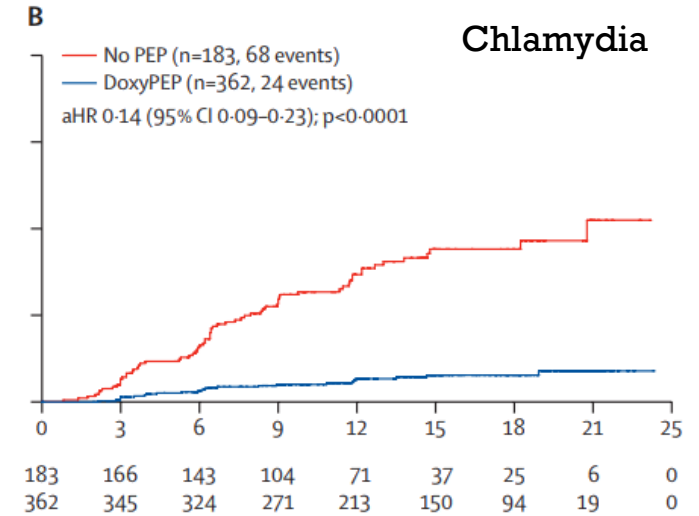
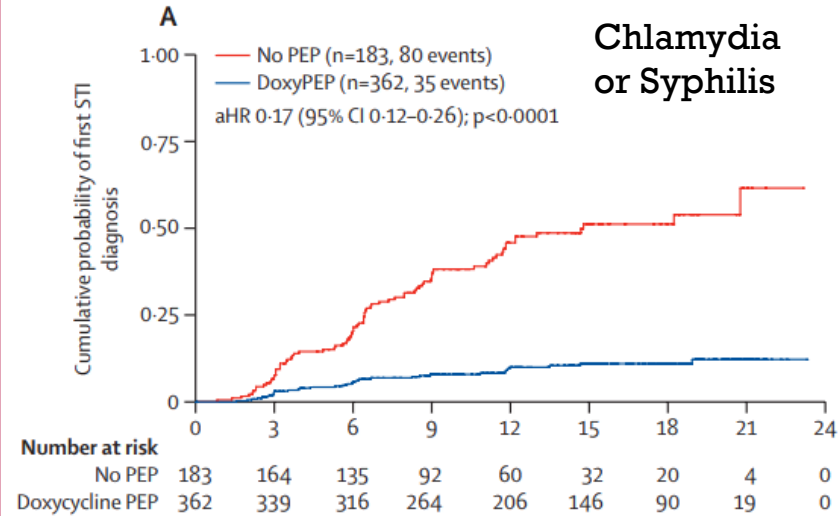
Population (n=556)

- 88% White
- Average age 40
- Average 2 STIs in past year
- 10 partners in past 3 months
- 23% w/STI at enrollment

Median 6 pills/month

70% self reported coverage

Molina JM, et al. Lancet Infect Dis. 2024 May 23:S1473-3099(24)00236-6

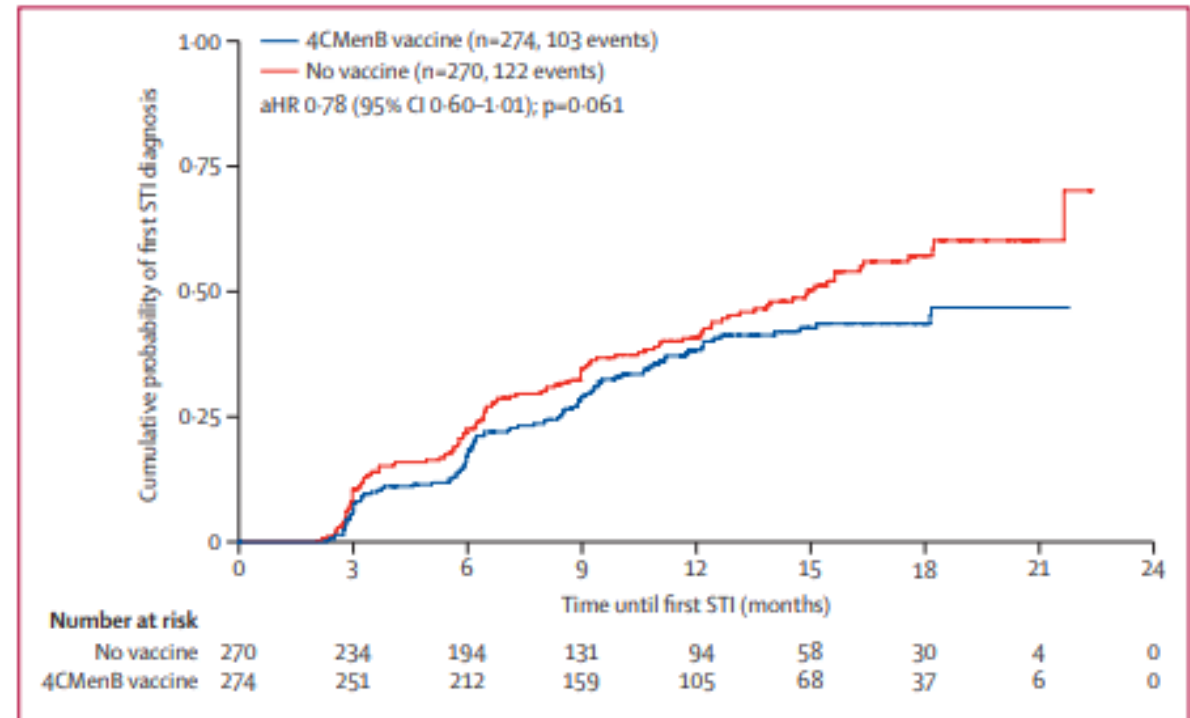


# DOXYVAC RESULTS – MENB VACCINE

- Data for MenB vaccination to prevent GC was inconclusive
- Small benefit (~20-30%) possible
- Similar rates of cumulative as well as symptomatic infections
- Phase 3 trial of gonorrhoea specific vaccine ongoing



GSK receives US FDA Fast Track designation for investigational vaccine against gonorrhoea

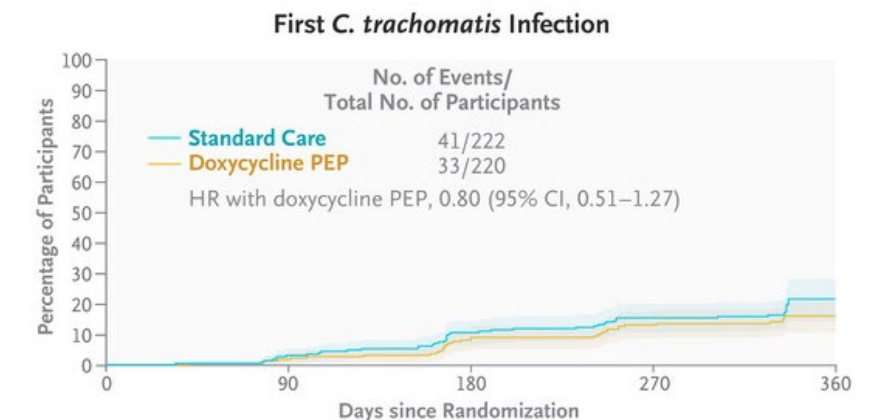
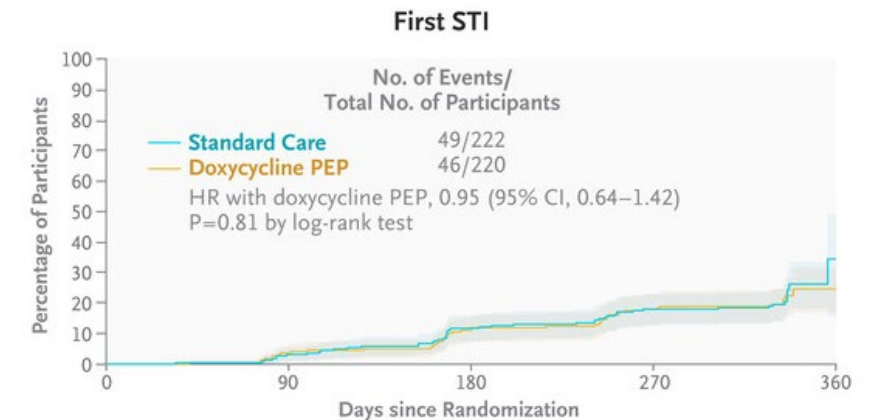
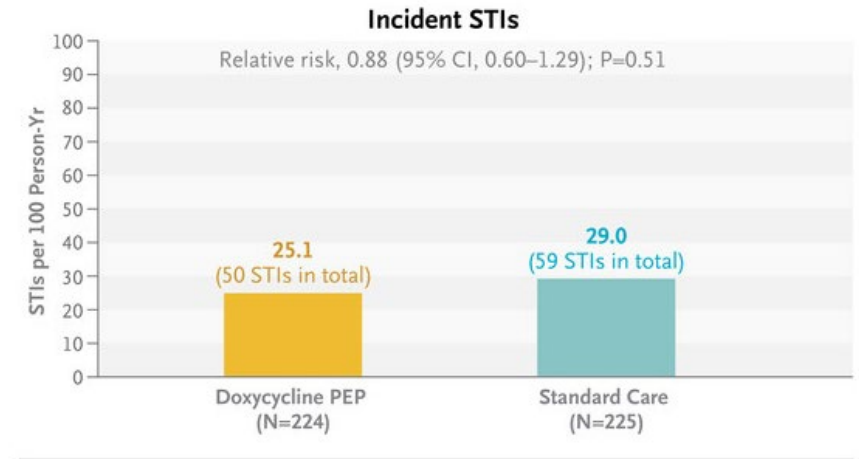


Molina JM, et al. Lancet Infect Dis. 2024 May 23:S1473-3099(24)00236-6

# DPEP-KE

- 1:1 open-label randomized trial
  - Intervention: 200mg doxycycline within 72hrs of sex
  - SOC: quarterly STI screening and treatment
- Population (n=449) in Kimusu, Kenya
  - Average age 24
  - 70% never married
  - Average 2 partners in the past 3 months
  - 18% with STI at enrollment
  - Median of 4 doxyPEP doses/month
  - 80% sex acted covered with doxyPEP by self-report
- No difference in 1<sup>st</sup> STI or CT
  - Drug only detected in 56% of participants
  - 4 social harms reported in setting of unintentional disclosure of doxyPEP use

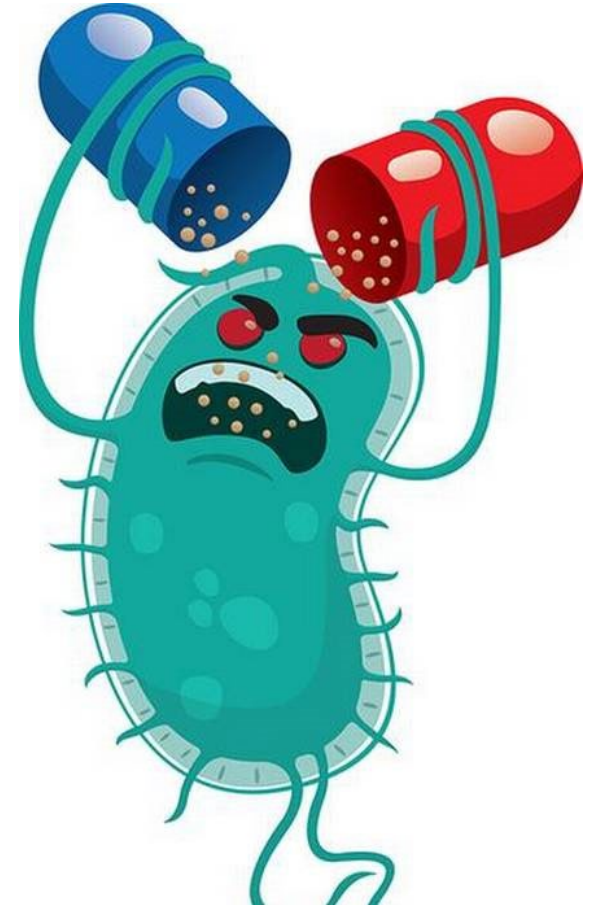
Stewart J, et al. N Engl J Med. 2023 Dec 21;389(25):2331-2340





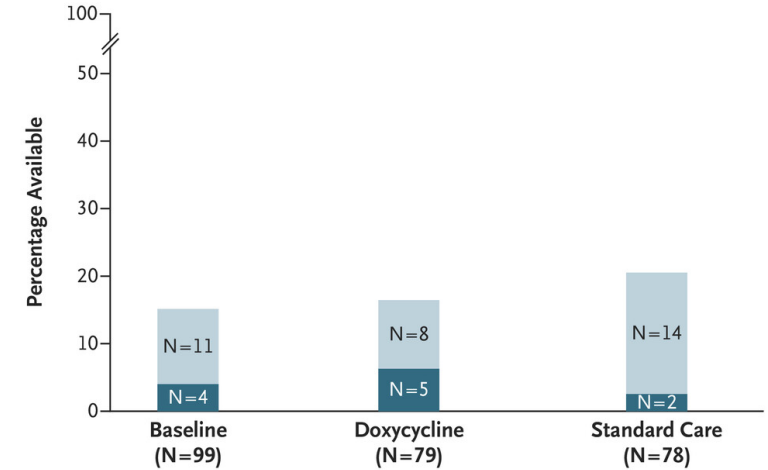
# CONCERN FOR ANTIMICROBIAL RESISTANCE

- Tetracycline resistance already seen in gonorrhea (higher in MSM)
- Chlamydia treatment failure seen in 5-23% of cases, however clear resistance to tetracycline not identified
- Mycoplasma genitalium (MG) emerging cause of NGU in MSM, seeing resistance to tetracycline
- No established standards for identifying or measuring doxycycline resistance in NG, CT, MG, or TP
- Concern for resistance of commensal flora (staphylococcus, streptococcus, etc)

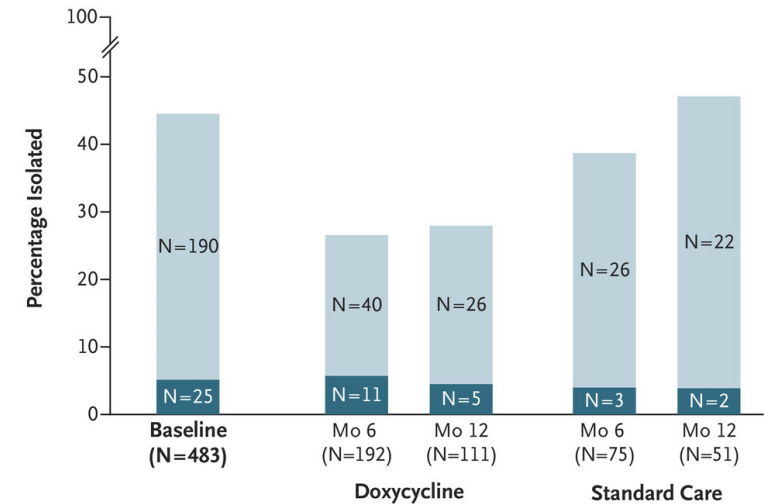


# Tetracycline (TCN) Resistance for GC and CT

## A *N. gonorrhoeae* Culture

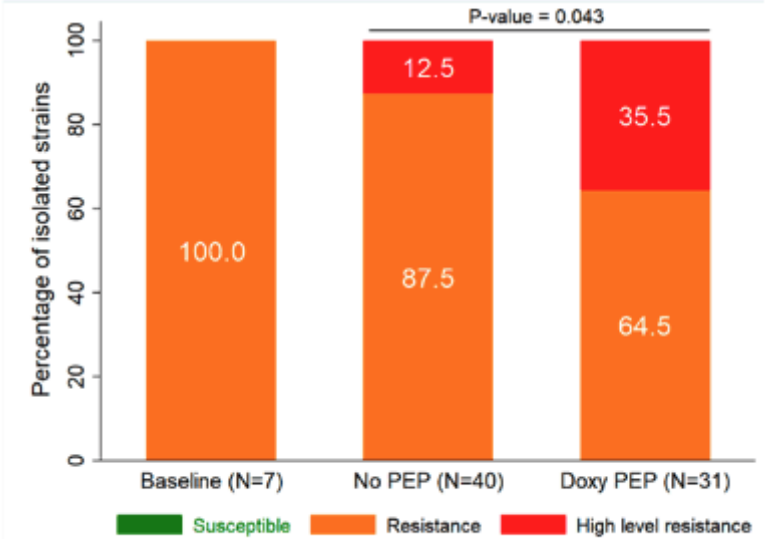


## B *S. aureus* Culture



- **GC:**
  - 78 cultures available for resistance testing (17% of PCR positive events)
  - Tetracycline MICs determined by Etest
  - Resistance using EUCAST 2023 breakpoints
    - Resistance: MIC > 0.5 mg/L
    - High level resistance: MIC > 8 mg/L
- **CT:**
  - 4/23 swabs tested for TCN-R in culture: no resistance (but none from PEP arm)
  - 68/126 PCR+ swabs with 16S rRNA sequences: no TCN-R mutation (only 8 from PEP arm)

### Proportion of TCN-Resistant GC



**Figure 4. Antimicrobial Resistance and Culture Positivity in *Neisseria gonorrhoeae* and *Staphylococcus aureus*.**  
 In Panel A, the bar height represents *N. gonorrhoeae* cultures obtained from participants with lab-confirmed gonorrhea at baseline and for adjudicated gonorrhea end points according to study group during follow-up. Of the gonorrhea diagnoses, 44 of 256 *N. gonorrhoeae* infections (17.2%) had data available for resistance testing. The dark shading represents high-level tetracycline resistance (minimum inhibitory concentration [MIC],  $\geq 2$   $\mu\text{g}$  per milliliter). The light shading represents *N. gonorrhoeae* without high-level tetracycline resistance. Gonorrhea culture was performed through the Centers for Disease Control and Prevention (CDC) Strengthening the United States Response to Resistant Gonorrhea program, and tetracycline-resistance testing was performed by agar dilution through the CDC Antimicrobial Resistance Laboratory Network. With respect to Panel B, all the participants had oropharyngeal swabs obtained at enrollment and at months 6 and 12, which were cultured for *S. aureus*. The bar height represents the percentage culture-positive for *S. aureus*, and the dark shading represents specimens with doxycycline resistance by ETEST (MIC,  $\geq 16$   $\mu\text{g}$  per milliliter).

Resistance for GC and CT)  
 Luetkemeyer AF, et al. N Engl J Med. 2023 Apr 6;388(14):1296-1306

# OTHER RESISTANCE CONCERNS

- Widespread use of doxyPEP will select for tetracycline-resistant gonorrhea
- Limited long-term benefit for extragenital GC
- DoxyPEP will **not** be our answer to reducing GC infections
- Theoretical risk of selective dual-resistance GC isolates (bacteria resistant to TCN as well as cephalosporin)
  
- **We must weigh these real AMR concerns with the significant reductions seen in syphilis and chlamydia infections**

Study	Population (n)	DoxyPEP use	Primary Finding	Comments
IPERGAY Molina et al. Lancet ID 2018	HIV-neg MSM (n=232)	3.4 doses/mo (86% coverage)	<b>47% reduction</b> in first STI No difference in GC	homogenous study population
DoxyPEP Luetkemeyer et al. NEJM 2023	MSM/TWSM (HIV-neg n=327) (LWH n=174)	4 doses/mo (86% coverage)	<b>66% reduction</b> in first STI GC, CT, and syphilis	<5% TWSM
DOXYVAC Molina et al. Lancet ID 2024	HIV-neg MSM (n=700)	3.5 doses/mo (83% coverage)	<b>65% reduction</b> in first STI GC, CT, and syphilis	homogenous study population
dPEP-KE Stewart et al. NEJM 2023	HIV-neg ciswomen (n=449)	? doses/mo (78% coverage)	<b>No reduction</b> in first STI	4 social harms reported in doxyPEP group
SYPHILAXIS Haire et al. NCT03709459	HIV-neg MSM (enrolling)			
DISCO Grennan et al. NCT04762134	MSM (not yet enrolling)			

# SO WHERE DO WE GO FROM HERE?

Several questions/concerns remain:

- Long term safety and AE data needed
- Clearly identify target population
- Monitoring resistance to STIs as well as commensal flora
- Education efforts, distinguishing HIV PEP/PrEP from Doxy PEP

Urgency of ongoing STI burden on MSM and TWSM compels us to act now

# LOCAL AND NATIONAL DOXYPEP GUIDANCE

**Table 2. Current Published Doxy-PEP Guidance**

Agency	Patient Population and Eligibility	Strength of Guidance	Screening Recommendations	Comments
<i>National and International Agencies</i>				
The Australasian Society for HIV, Viral Hepatitis, and Sexual Health Medicine (ASHM) [26]	GBMSM with recent syphilis diagnosis, 2 or more bacterial STIs with past 12 mo, anticipated increased STI vulnerability, concurrent sexual male and cisgender female partners	Consider	STI screening should continue in line with guidelines for GBMSM; screening for NG, CT, TP every 3 mo	Doxy-PEP should be considered primarily for the prevention of syphilis in GBMSM
British Association of Sexual Health and HIV (BASHH)/UK Health Security Agency (UKHSA) [27]	Doxycycline taken as PEP or PrEP for syphilis or chlamydia is not endorsed	Not recommended	Routine HIV and STI among patients who chose to use doxy-PEP	...
European AIDS Clinical Society (EACS) [28]	Discussion on the use of doxycycline PrEP and PEP should be undertaken in men with HIV with recent bacterial STI	Consider	...	Offer if locally available and following local guidance
German STI Society/ Deutsche STI-Gesellschaft (DSTIG) [29]	MSM and TGW with recurrent syphilis infections, bacterial STIs in the past 6 mo, sex with 10 or more male partners in the last 6 mo, stimulant use during sex, or group sex	Consider	Screen for HIV, syphilis, NG, CT at initiation and every 3–6 mo	Narrow use restricted to MSM and TGW who meet criteria; broad implementation not recommended at this time
International Antiviral Society—USA (IAS-USA) [30]	Consider on a case-by-case basis for MSM and TGW highly vulnerable for acquiring syphilis, chlamydia, or gonorrhea	Consider	...	...
US Centers for Disease Control and Prevention (CDC) [31]	GBMSM and TGW with at least 1 bacterial STI in the past 12 mo	Consider	Screen for HIV, syphilis, NG, CT at initiation and every 3–6 mo	No recommendation for cisgender women, cisgender heterosexual men, transgender men, and other queer and nonbinary people
National Coalition of STD Directors [32]	GBMSM and TGW	Recommend	...	Need to develop equitable criteria for offering Doxy-PEP

<i>State and Local Health Agencies</i>				
California Department of Public Health [33]	MSM and TGW with ≥1 bacterial STI in the past 12 mo	Recommend	Screen for HIV, TP, NG, CT at initiation and every 3 mo	Offer Doxy-PEP using shared decision-making to all nonpregnant individuals, including people AFAB, who otherwise meet clinical criteria
Chicago Department of Public Health [34]	MSM and TGW with ≥1 bacterial STI in the past 12 mo AND report condomless anal or oral sexual contact with 1 or more cisgender men in the past 12 mo	Recommend	Comprehensive STI screening as well as safety monitoring at routine 3-mo intervals	Those with a history of syphilis should be prioritized
Michigan Department of Health and Human Services [35]	MSM and TGW with ≥1 bacterial STI in the past 12 mo	Recommend	...	...
New York City Department of Health and Mental Hygiene [36]	MSM and TGW with ≥1 bacterial STI in the past 12 mo	Recommend	Screen for HIV, CT, NG, and TP at initial doxy-PEP visit and every 3–6 mo	Consider prescribing Doxy-PEP on an episodic basis
New York State Department of Health AIDS Institute [37]	Cisgender men and TGW on HIV PrEP on living with HIV with ≥1 bacterial STI in the past 12 mo Cisgender men and TGW not on HIV PrEP or living with HIV	Recommend	Screen for HIV, CT, NG, and TP at least every 3 mo	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 on a case-by-case
Oregon Health Authority [38]	Cisgender men, transgender women, and nonbinary people assigned male at birth who have sex with people with a penis AND ≥1 bacterial STI in the past 12 mo	Recommend	Screen for HIV, syphilis, NG, CT at initiation and every 3 mo. Consider routine liver testing in those with or at risk for liver disease	Doxy-PEP may be effective for all people who have oral and anal sex with people with a penis regardless of gender identity and sex assigned at birth; use shared decision-making to help a patient decide if doxy-PEP is right
Public Health—Seattle & King County, Washington [39]	MSM and TGW with ≥1 bacterial STI in the past 12 mo	Consider	Regularly testing for HIV/STIs	Those with a history of syphilis should be prioritized
San Francisco Department of Public Health [40]	MSM and TGW with ≥1 bacterial STI in the past 12 mo AND report condomless anal or oral sexual contact with one or more cisgender men in the past 12 mo	Recommend	Screen for HIV, syphilis, NG, CT at initiation and every 3 mo. LFTs, renal function and a CBC should be checked periodically in people taking doxy-PEP for prolonged period	Those with a history of syphilis should be prioritized

Abbreviations: AFAB, assigned female at birth; CT, *Chlamydia trachomatis*; Doxy-PEP, doxycycline postexposure prophylaxis; GBMSM, gay, bisexual, and other men who have sex with men; HIV, human immunodeficiency virus; LFT, Liver function tests; MSM, other men who have sex with men; NG, *Neisseria gonorrhoea*; PEP, postexposure prophylaxis; PrEP, preexposure prophylaxis; STD, Sexually transmitted diseases; STI, sexually transmitted infection; TGW, transgender women; TP, *Treponema pallidum*.

# REAL WORLD DATA FROM SFDPH

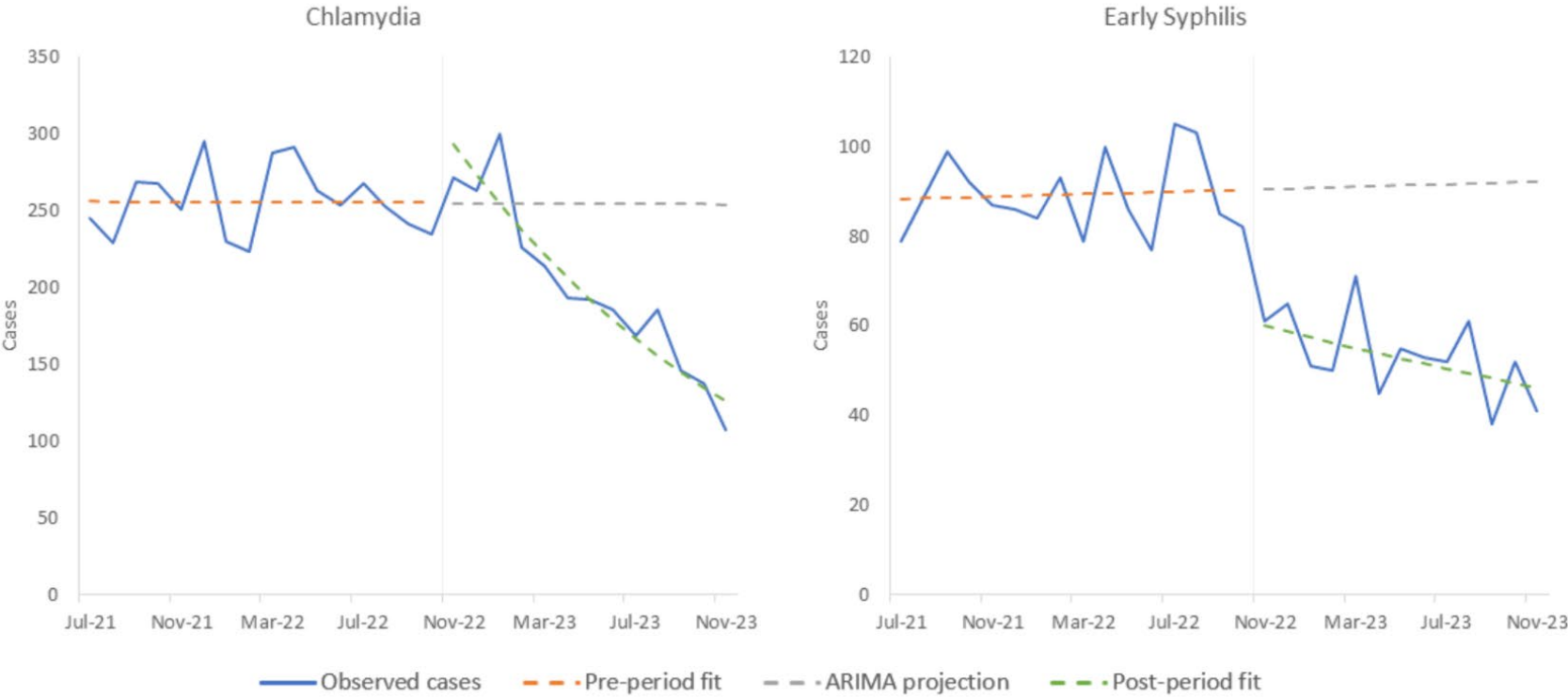


Figure. Observed and modelled chlamydia and early syphilis cases among MSM and TGW in San Francisco pre and post doxy-PEP implementation

# DÉJÀ-VU ALL OVER AGAIN?

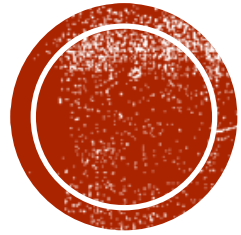
Striking similarities between HIV PrEP and DoxyPEP

- Novel biomedical intervention w/significant impact in priority populations
- Concerns of anti-microbial resistance/misuse
- Equity concerns regarding utilization and uptake
- Data in cisgender women are lacking

So, what's different now?

- Signals of higher interest in Black and Hispanic/Latinx men
- **WE SHOULD KNOW AND DO BETTER**





# QUESTIONS?



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## MATEC Resources

- National Clinician Consultation Center  
<http://nccc.ucsf.edu/>
  - HIV Management
  - Perinatal HIV
  - HIV PrEP
  - HIV PEP line
  - HCV Management
  - Substance Use Management
- AETC National HIV Curriculum  
<https://aidsetc.org/nhc>
- AETC National HIV-HCV Curriculum  
<https://aidsetc.org/hivhcv>

National PrEP Curriculum:  
<https://www.hivprep.uw.edu>

Hepatitis B Online: <https://www.hepatitisb.uw.edu>

Hepatitis C Online:  
<https://www.hepatitisc.uw.edu>

AETC National Coordinating Resource  
Center: <https://aidsetc.org/>

Additional Trainings: <https://matec.info>

