



**Department  
of Health**

# Getting Foxy with Doxy: Sexual Health Promotion and STI Prevention Update



**MEDICAL SOCIETY OF THE  
STATE OF NEW YORK**  
ORGANIZED 1807

**Commissioner's Medical Grand Rounds**

Dr. James McDonald, MD, MPH, Commissioner

SEPTEMBER 11<sup>TH</sup>, 2024 • NOON – 1 PM EDT

# Opening Remarks

**Dr. James McDonald, MD, MPH**

**New York State Commissioner of Health**

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\*\*John Maese, MD has disclosed that he owns stock in Eli Lilly, Johnson & Johnson, Danaher Corp, Takeda Pharmaceutical Co Ltd, and Bausch Health Companies Inc.

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# **Sexually Transmitted Infections in New York State: An Epidemiologic Overview**

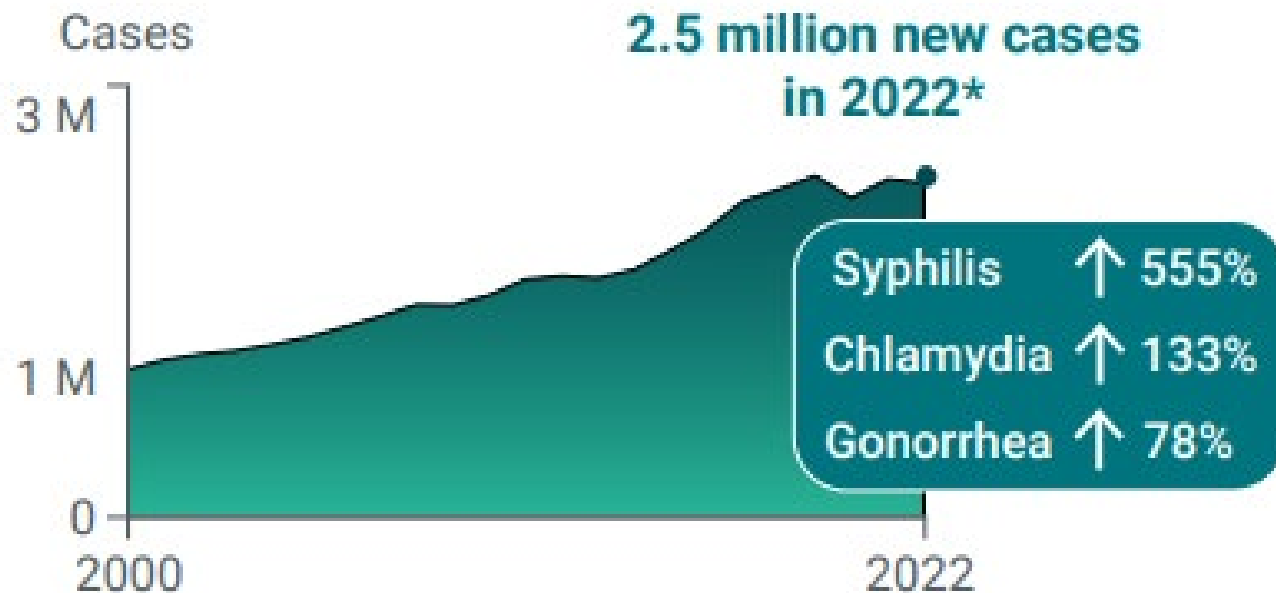
**Commissioner Grand Rounds  
September 11, 2024**

**Rachel Hart-Malloy, PhD, MPH**  
Director, Office of Sexual Health and Epidemiology  
AIDS Institute  
New York State Department of Health

# National trends show sustained acceleration in the three notifiable bacterial sexually transmitted infections.

## STI Overview

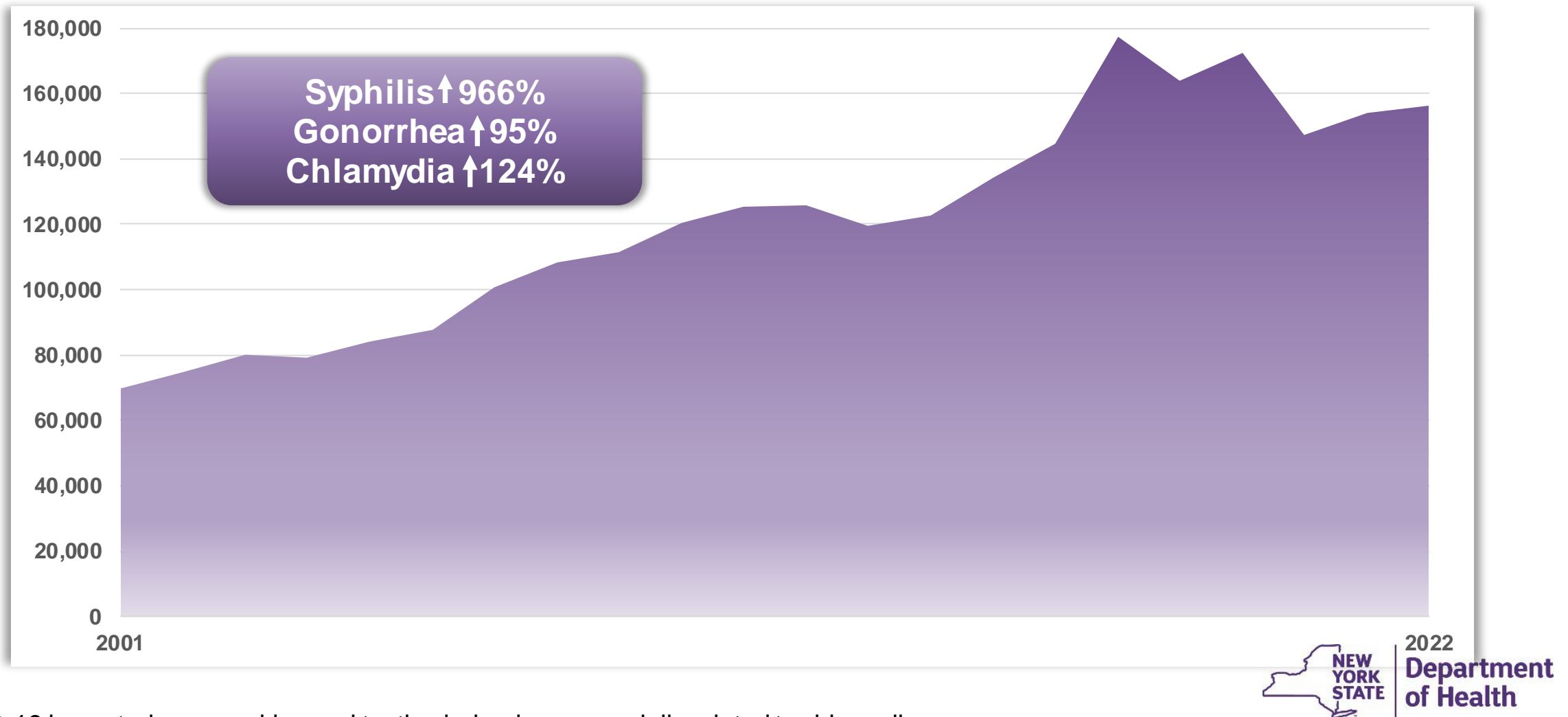
Chlamydia, gonorrhea, and syphilis cases have been increasing for years.



People most affected by STIs include:

- Adolescents and people aged 15-24 years
- Gay, bisexual, and other men who have sex with men
- Pregnant people
- People from some racial and ethnic minority groups

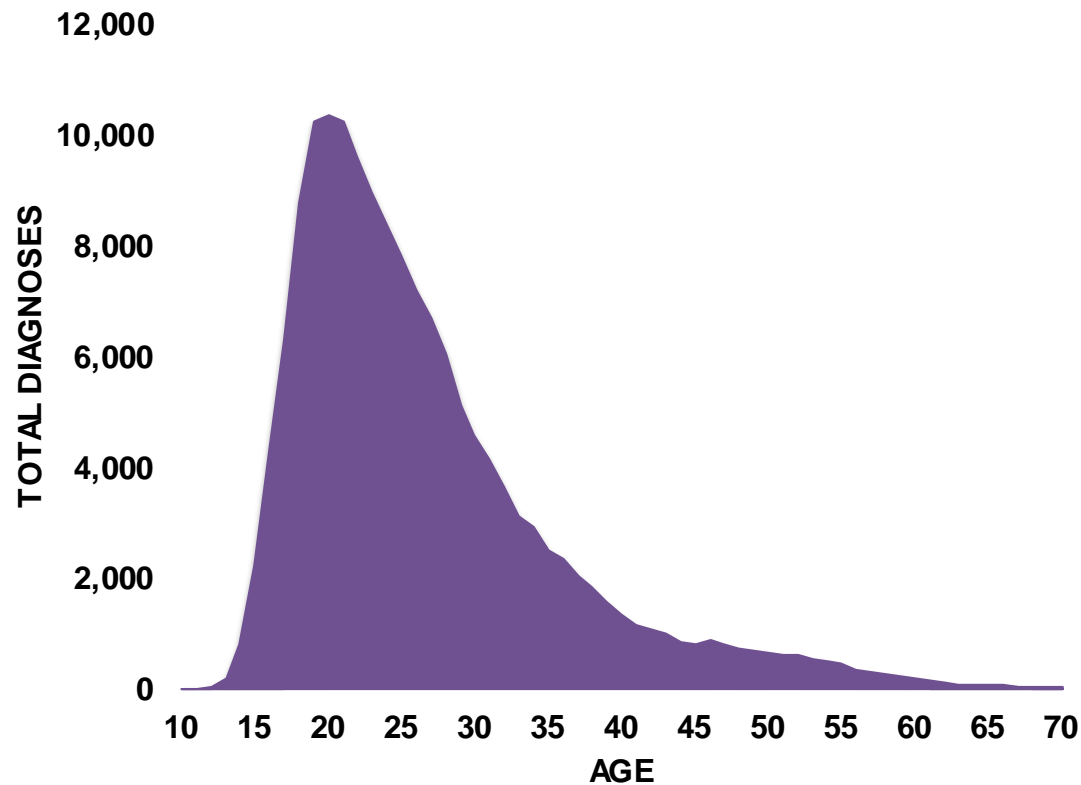
## New York State has experienced similar trends over time with gonorrhea, chlamydia and syphilis increasing over time.\*



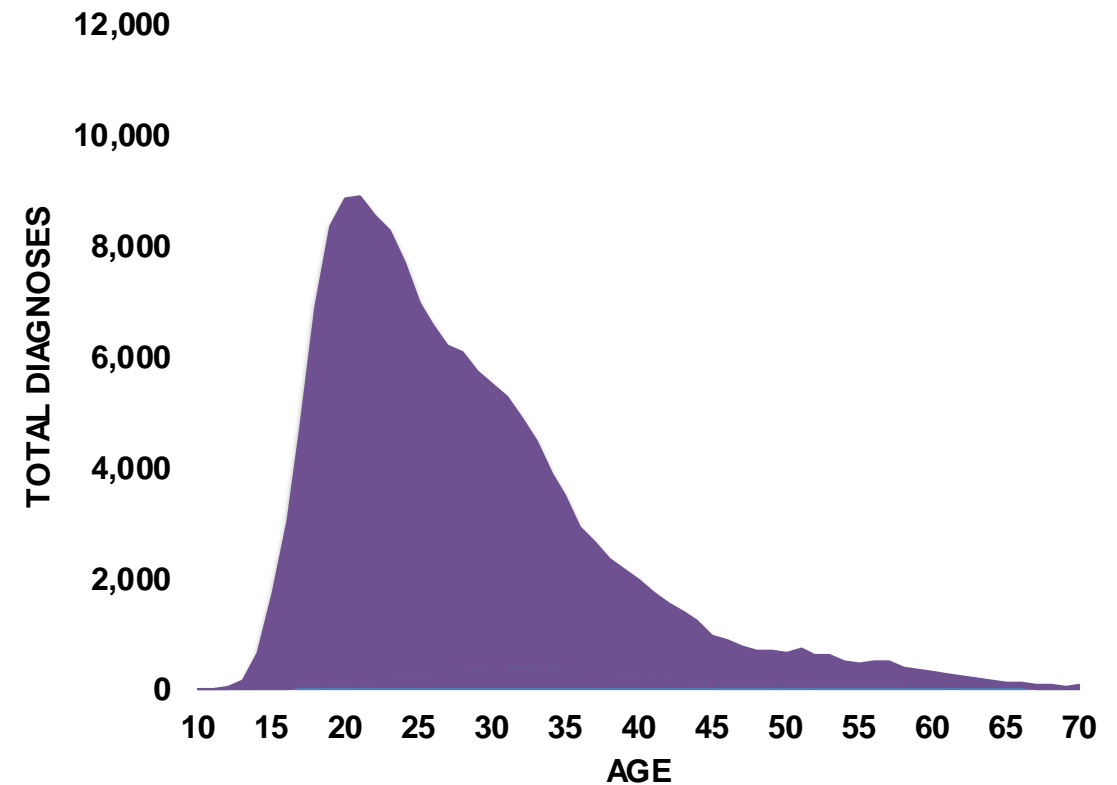
\*COVID-19 impacted care seeking and testing behaviors, especially related to chlamydia

# While sexually transmitted infections\* among younger persons in New York State remains an area of concern, the epidemic has been shifting.

In 2017, 55% of infections were diagnosed among people younger than 26 years old



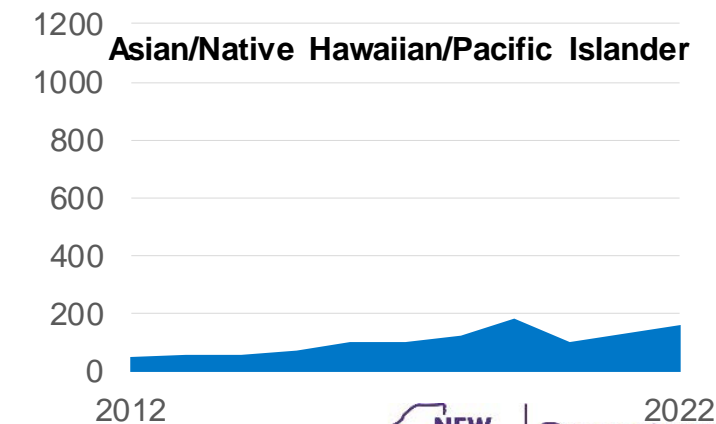
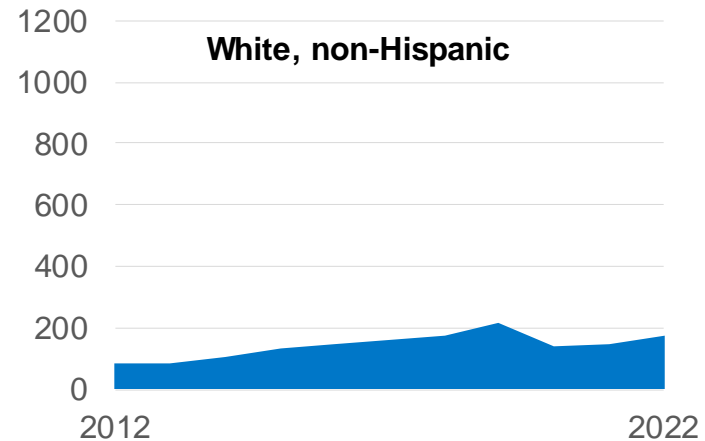
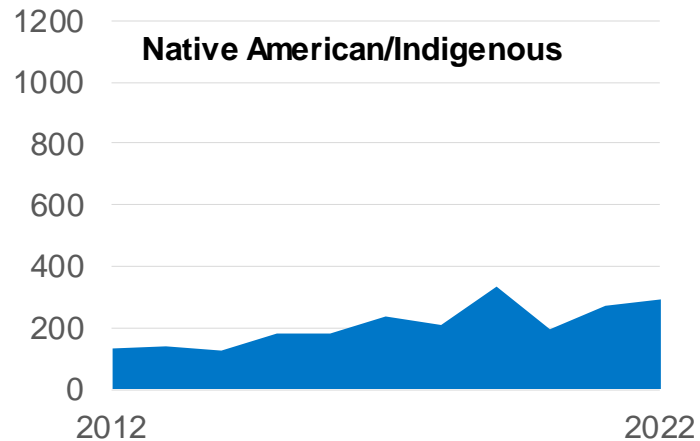
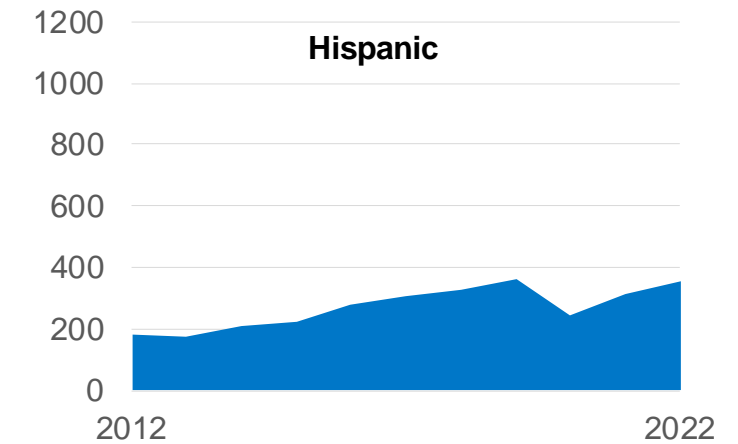
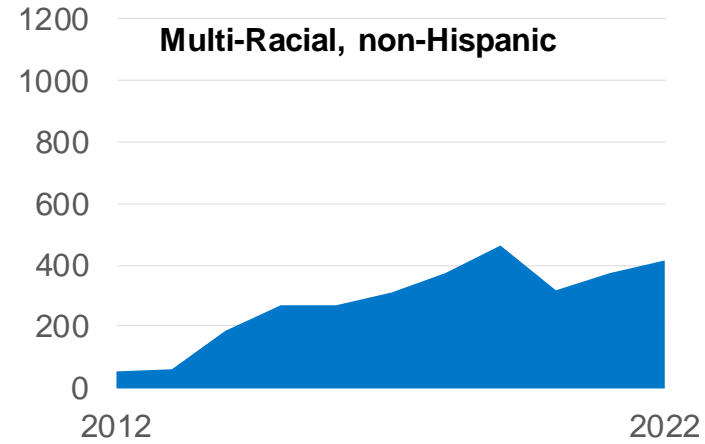
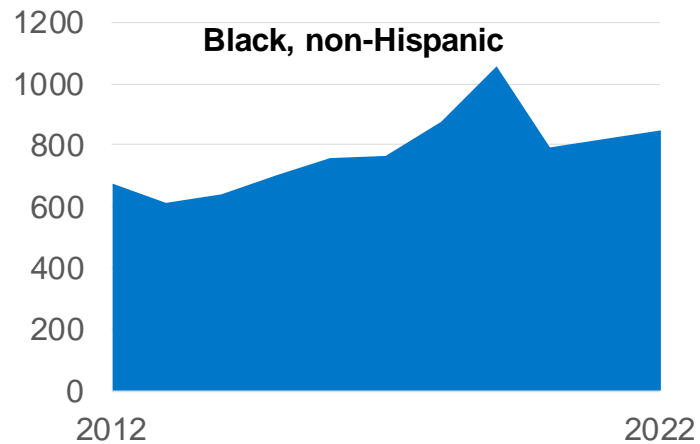
By 2022, this shifted to 47% of diagnoses were among those under 26 years of age



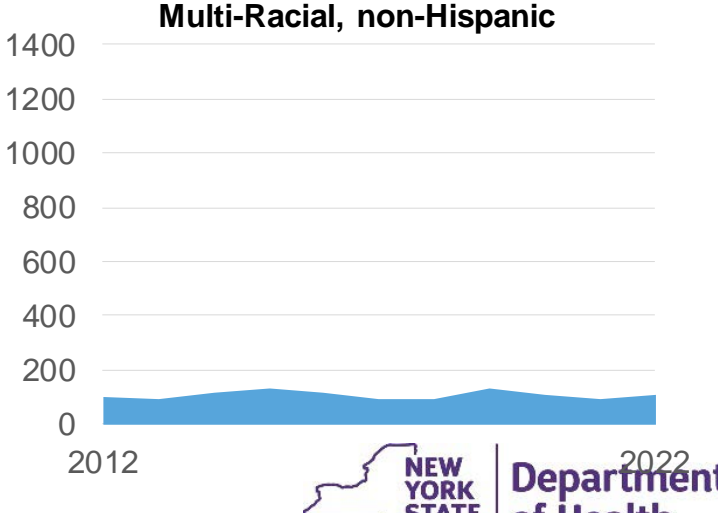
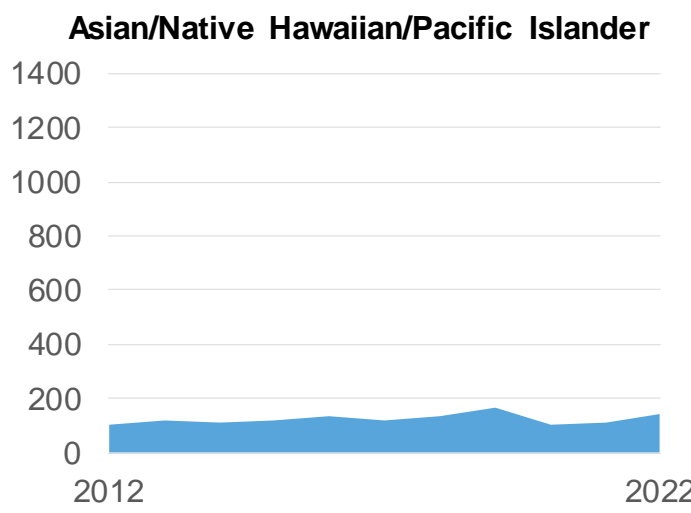
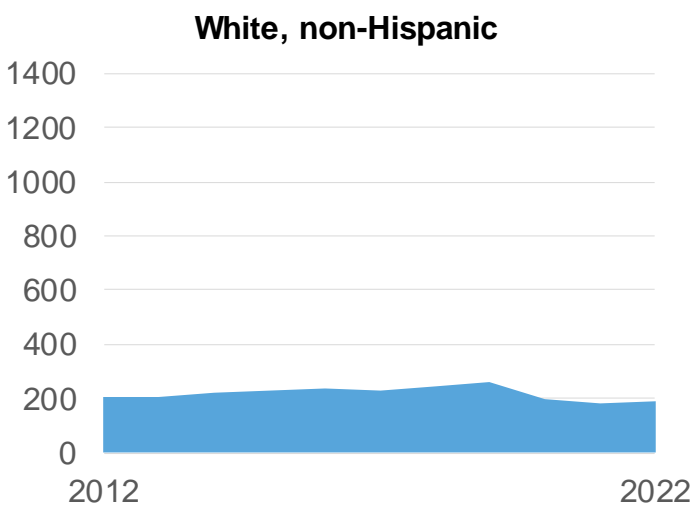
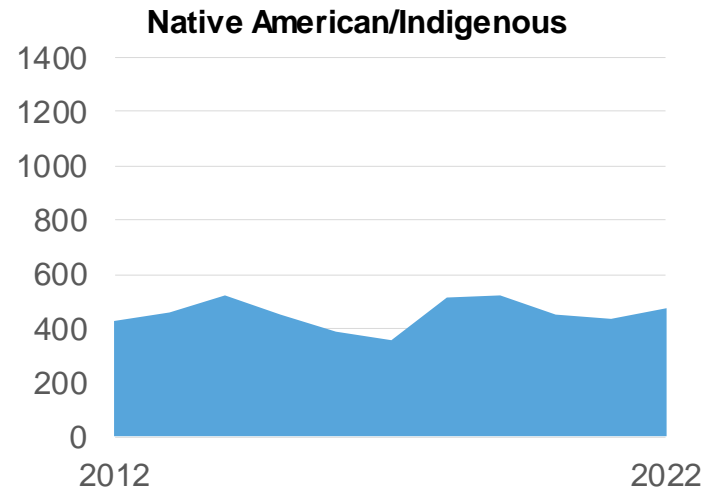
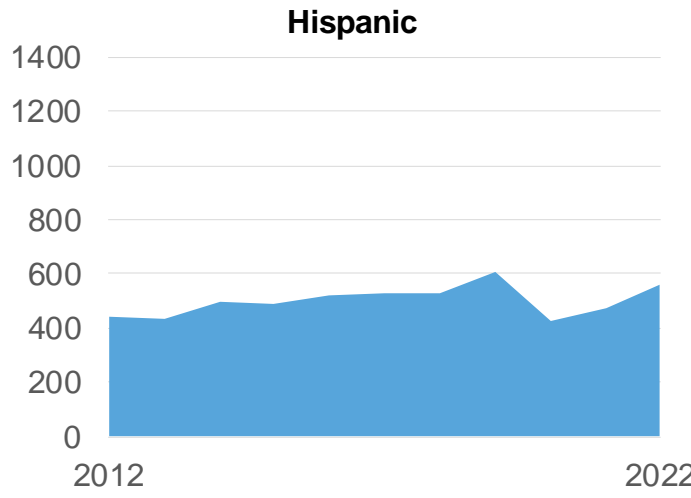
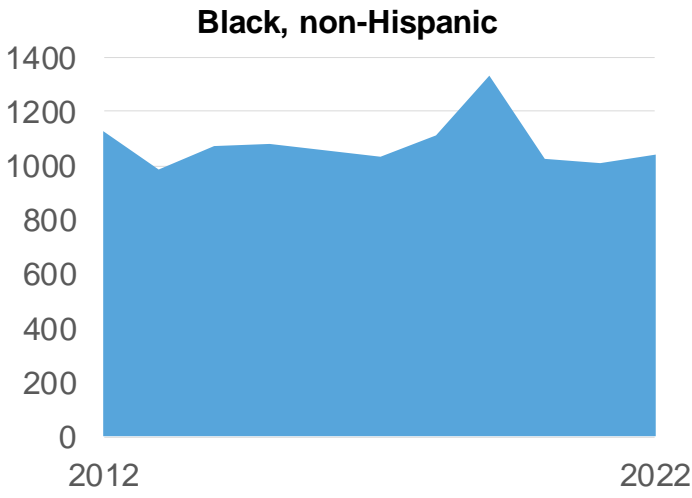
\*includes chlamydia, gonorrhea, and early syphilis reported in New York State

# Black, non-Hispanic persons are disproportionately impacted by sexually transmitted infections.

Chlamydia age-adjusted rates among males per 100,000 in New York State, 2012–2022

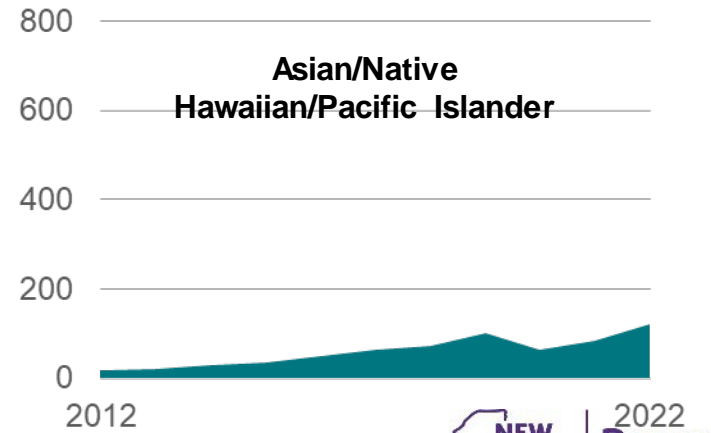
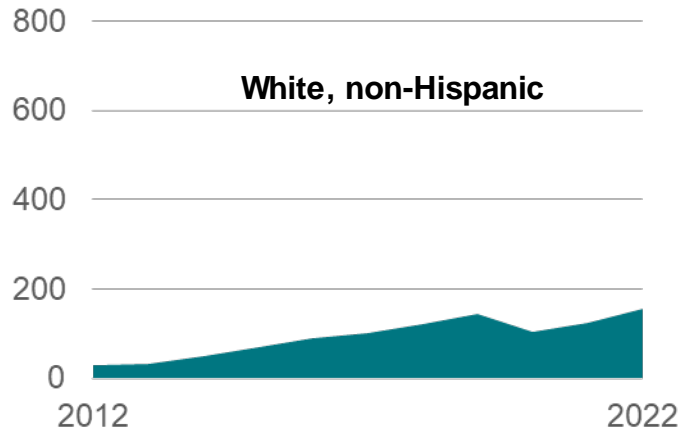
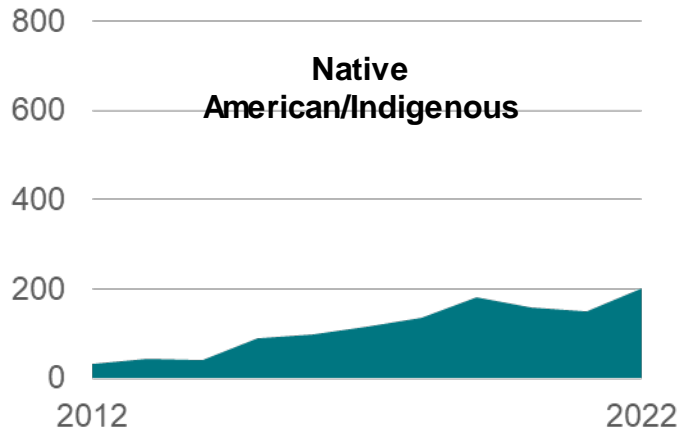
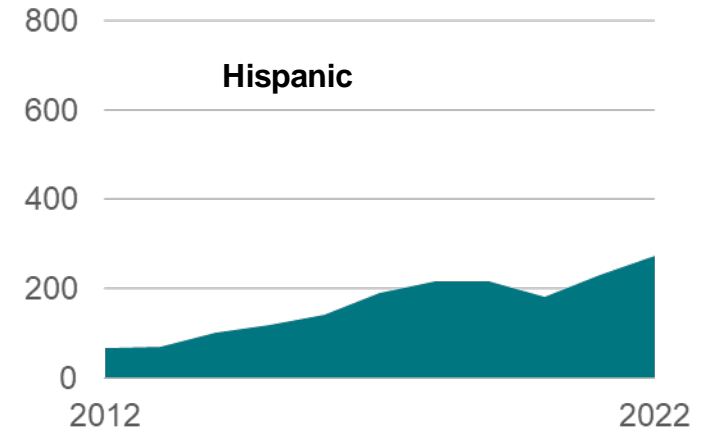
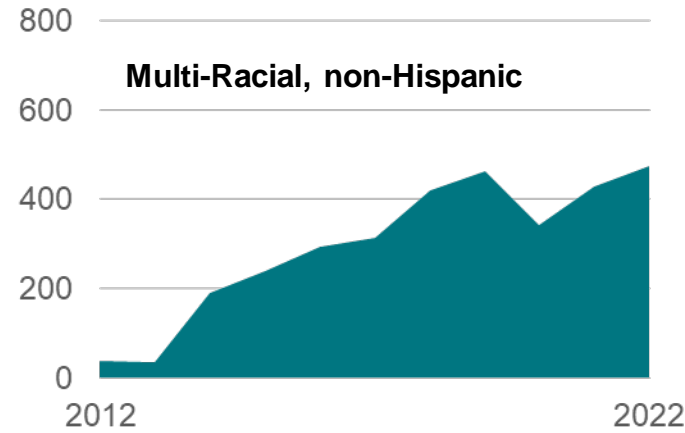
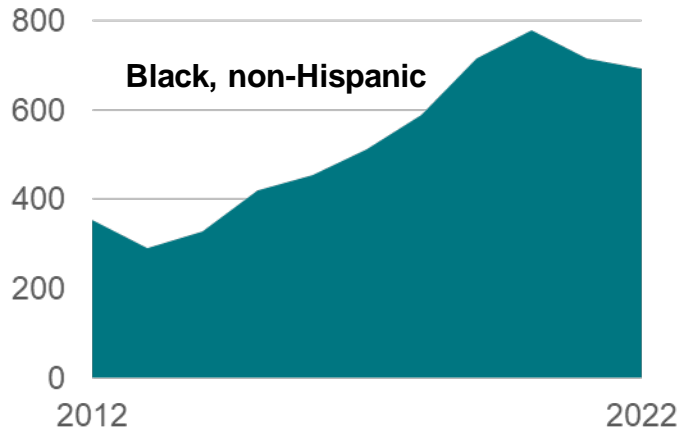


# Chlamydia age-adjusted rates among females by race/ethnicity in New York State, 2012-2022



# Gonorrhea rates among males by race/ethnicity

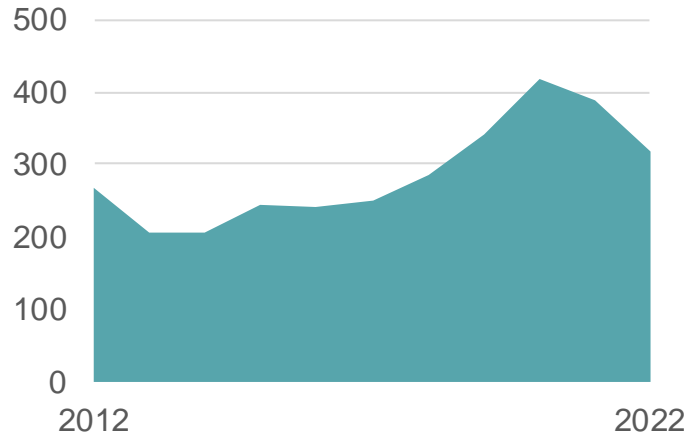
Gonorrhea age-adjusted rates per 100,000 in New York State, 2012–2022



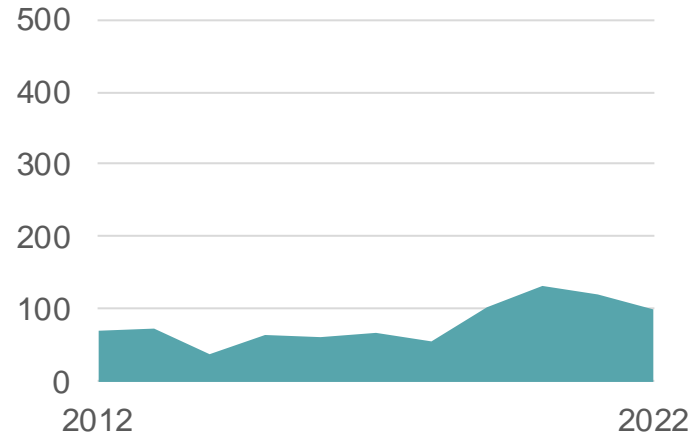
# Gonorrhea rates among females by race/ethnicity

Gonorrhea age-adjusted rates per 100,000 in New York State, 2012–2022

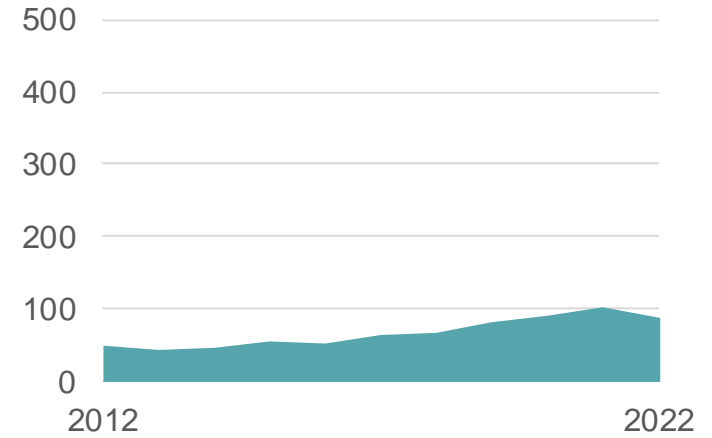
### Black, non-Hispanic



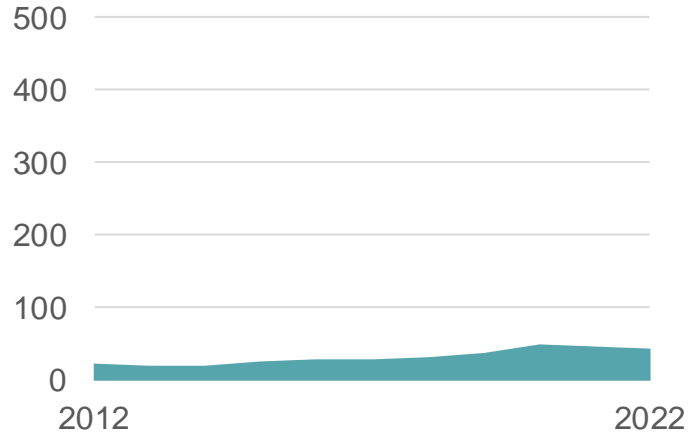
### Native American/Indigenous



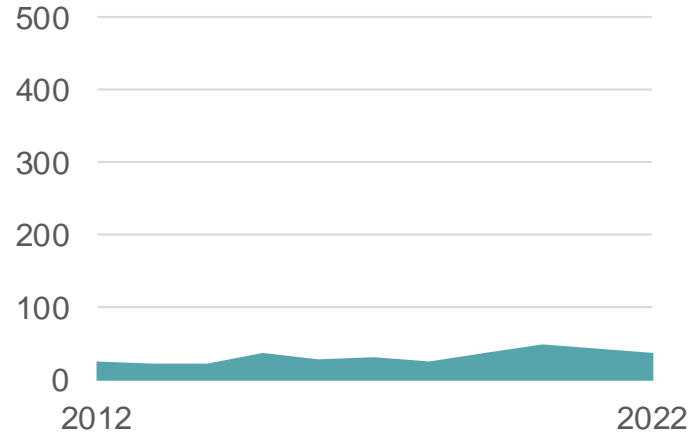
### Hispanic



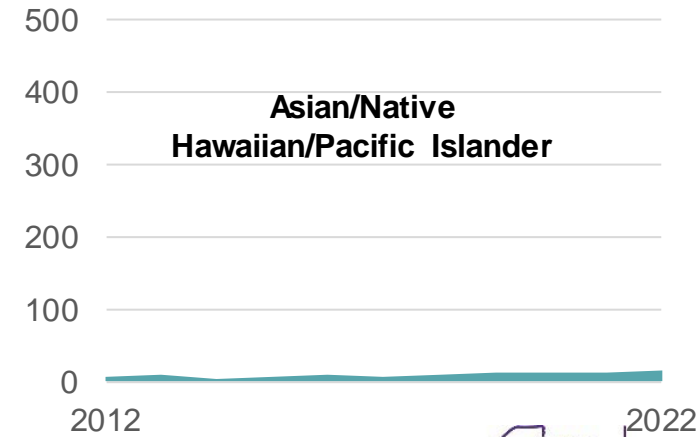
### White, non-Hispanic



### Multi-Racial, non-Hispanic

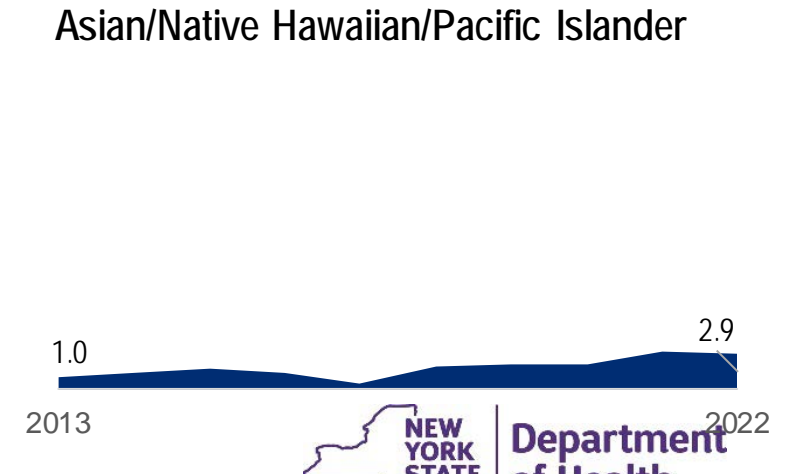
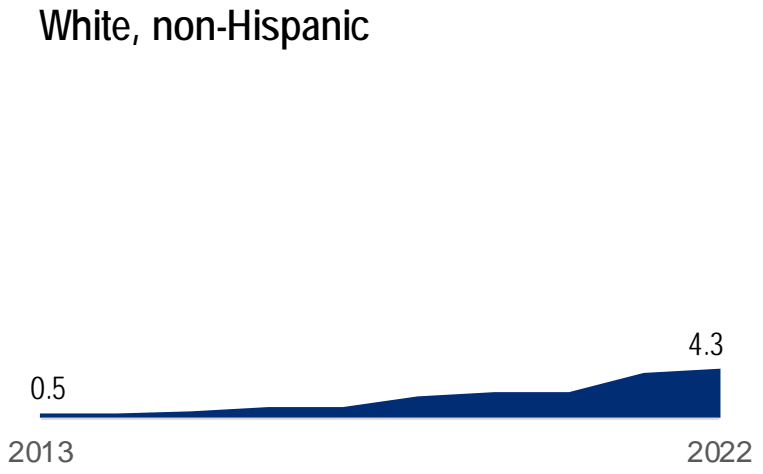
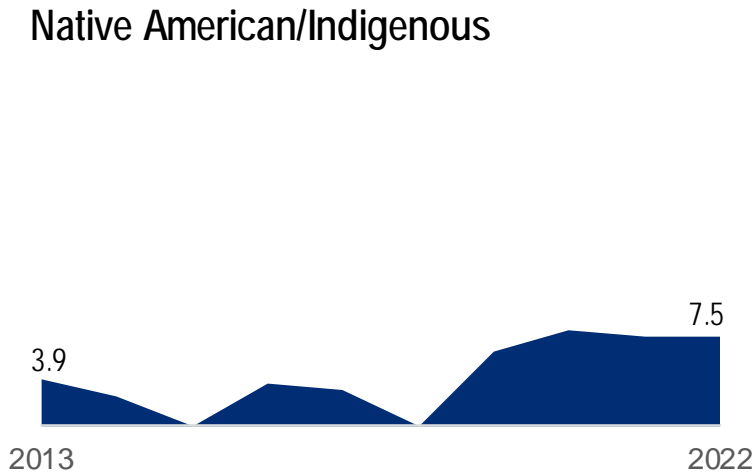
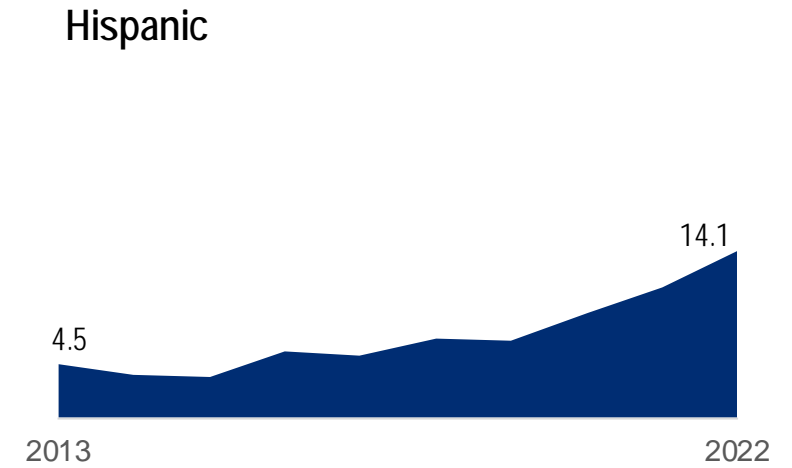
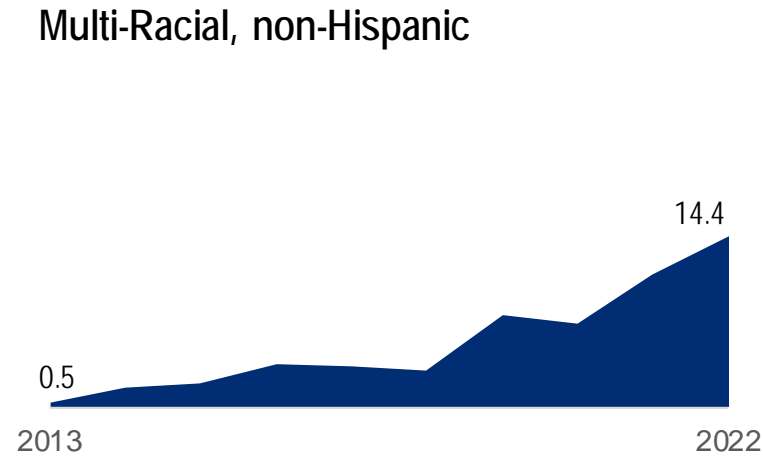
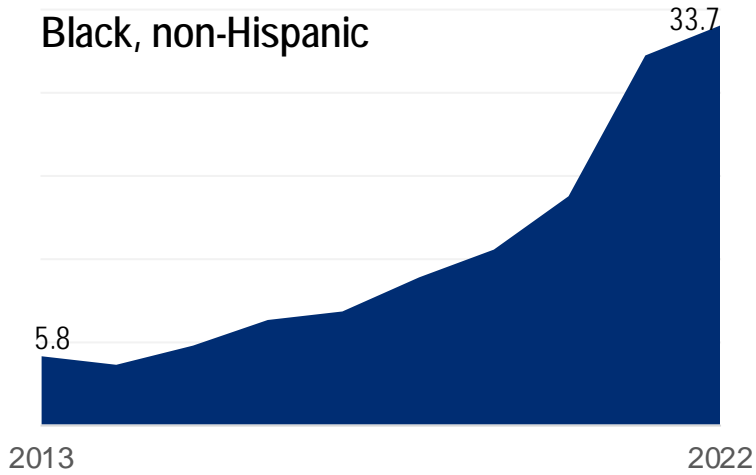


### Asian/Native Hawaiian/Pacific Islander



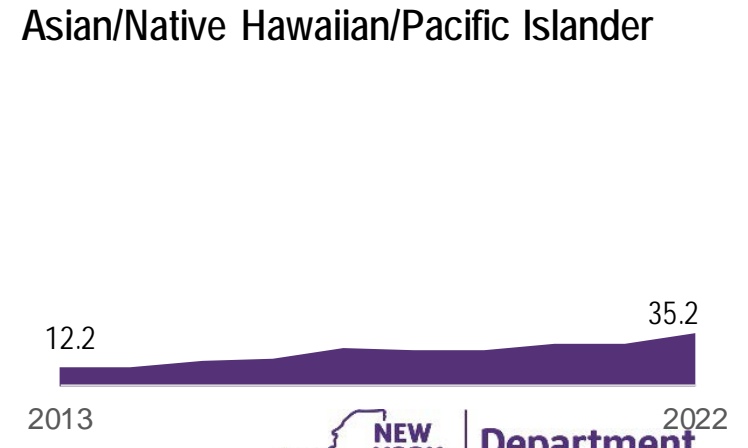
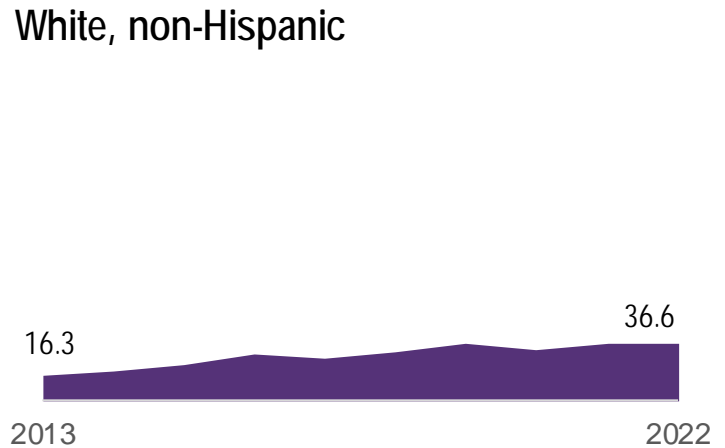
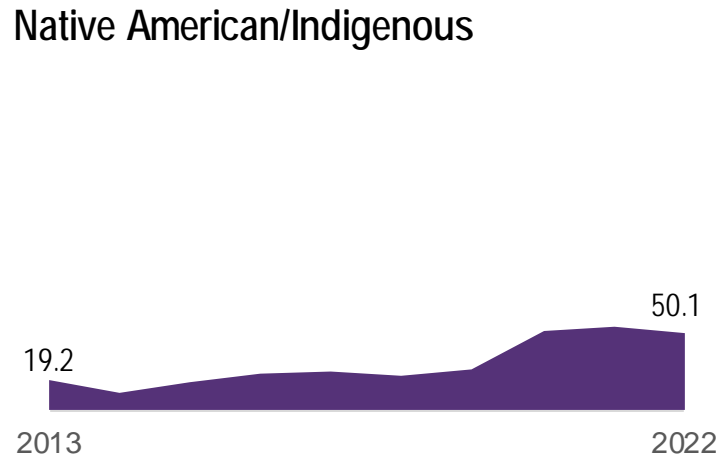
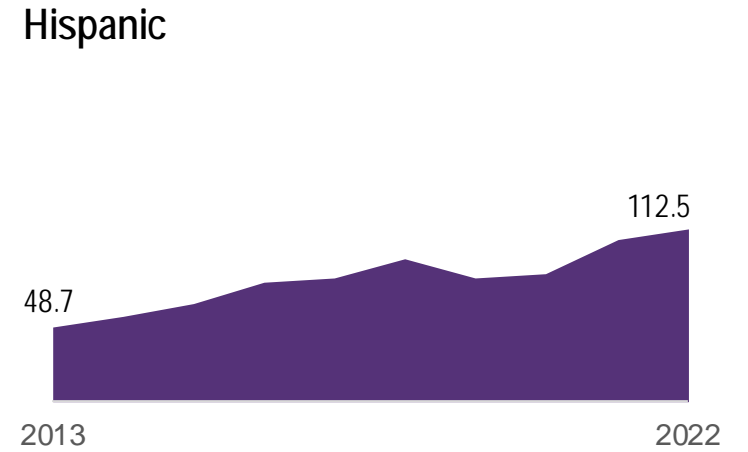
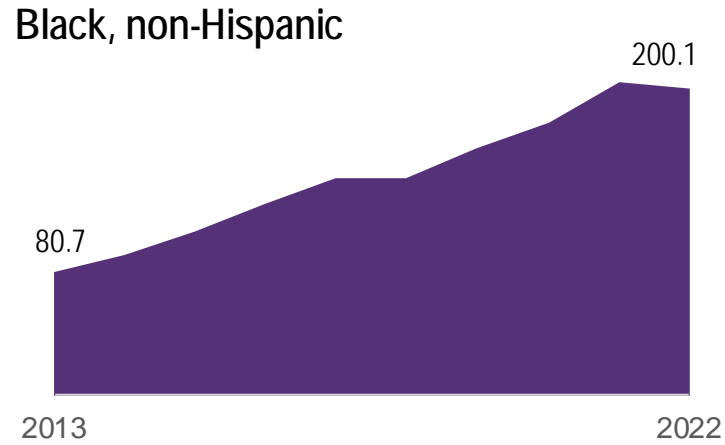
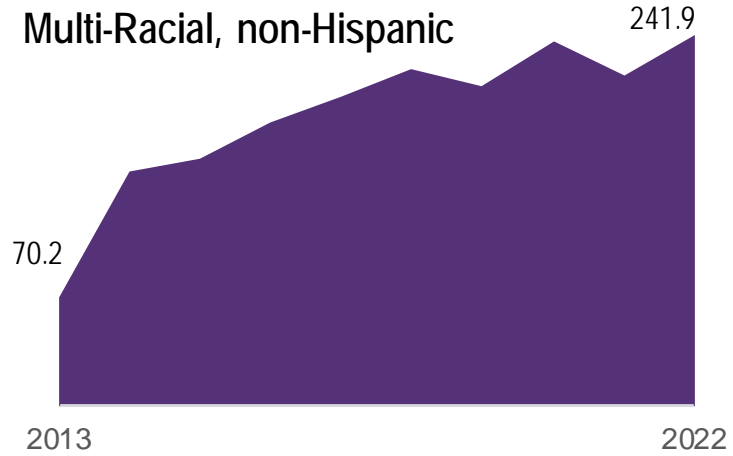
**While females identifying as Black, non-Hispanic continue to be disproportionately impacted by early syphilis, the greatest increases have been among those identifying as Multi-Racial, non-Hispanic.**

Age-adjusted early syphilis rate per 100,000 females by race/ethnicity and year, New York State, 2013–2022



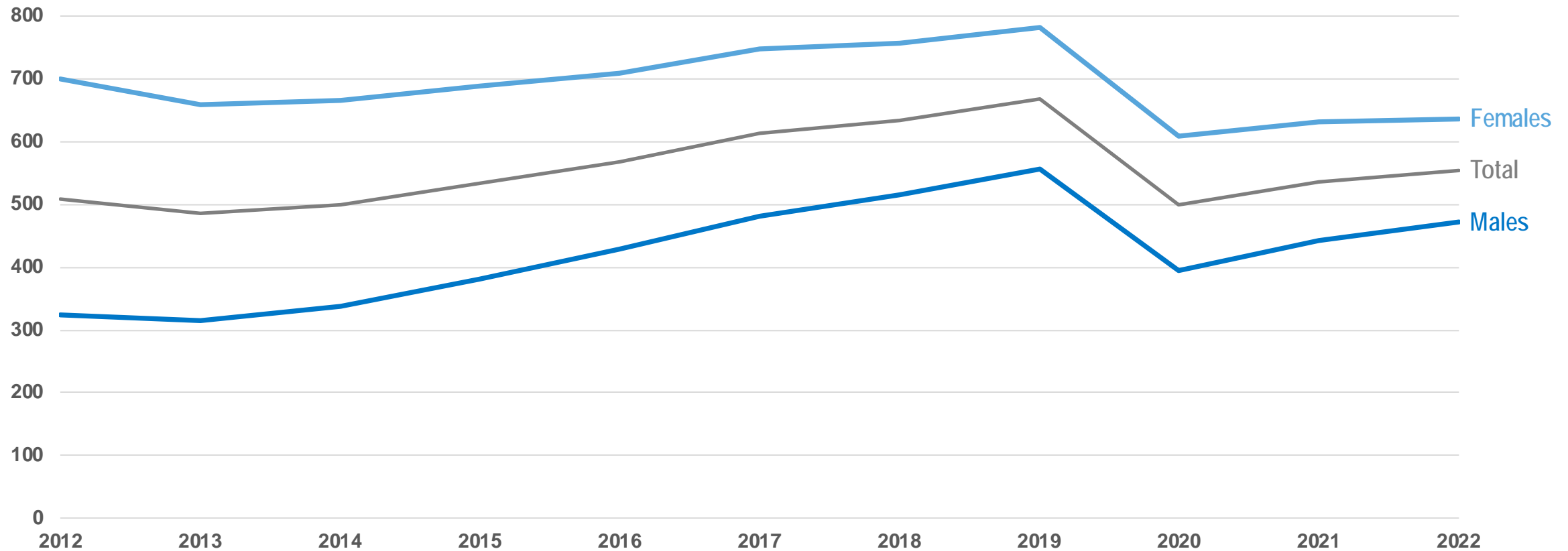
# Males identifying as Multi-Racial, non-Hispanic and Black, non-Hispanic continue to be disproportionately impacted by early syphilis.

Age-adjusted early syphilis rate per 100,000 males by race/ethnicity and year, New York State, 2013–2022



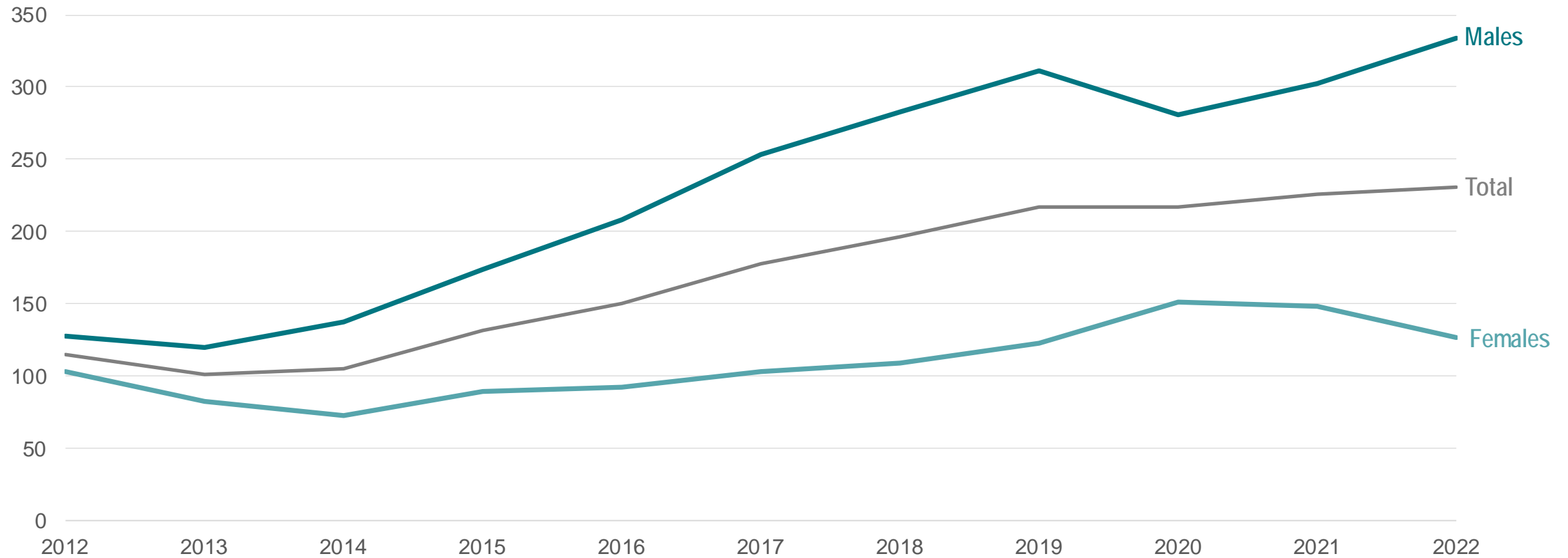
# While chlamydia rates remain greater among females, differences by sex at birth have slowly decreased over time

Chlamydia age-adjusted rates per 100,000 population in New York State, 2012–2022



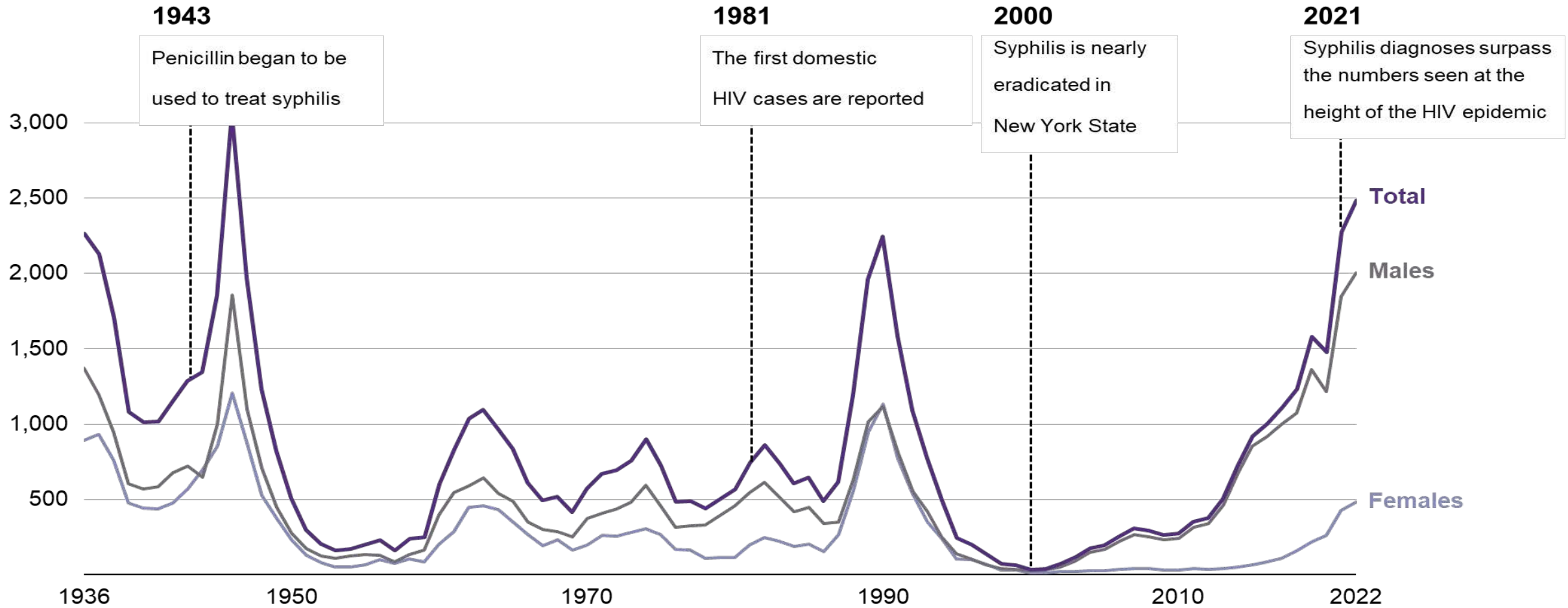
# Gonorrhea rates reached a ten-year high in 2022, driven by three consecutive years of increases among males

Gonorrhea age-adjusted rates per 100,000 in New York State, 2012–2022



# Syphilis is surging for the third time in a century

Early syphilis diagnoses by sex in New York State (excluding New York City), 1936–2022



# Primary & Secondary syphilis diagnoses among females aged 15-44 have been increasing over time, with implications for syphilis in newborns.

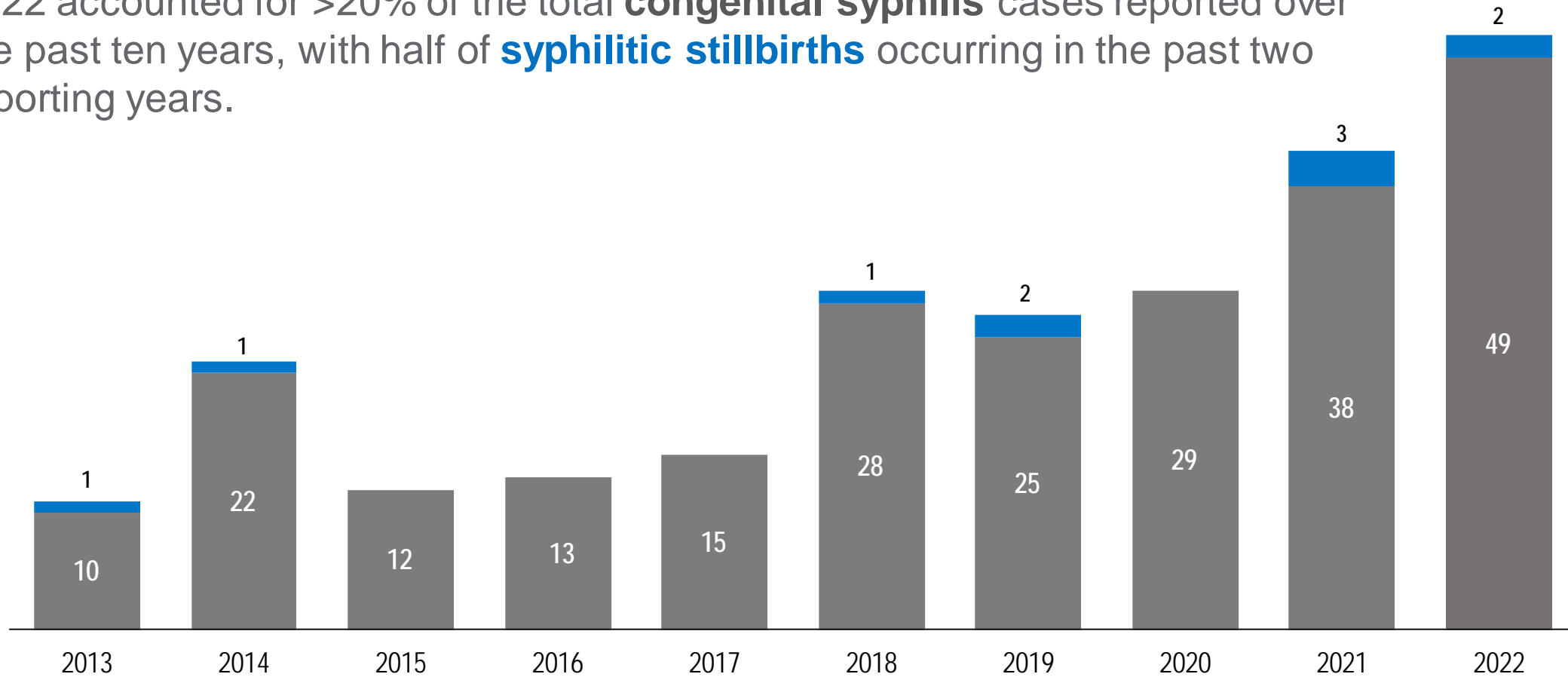
Although, rise in syphilis was increasing in men who have sex with men, the new modern syphilis epidemic among females suggests heterosexual transmission on the rise.



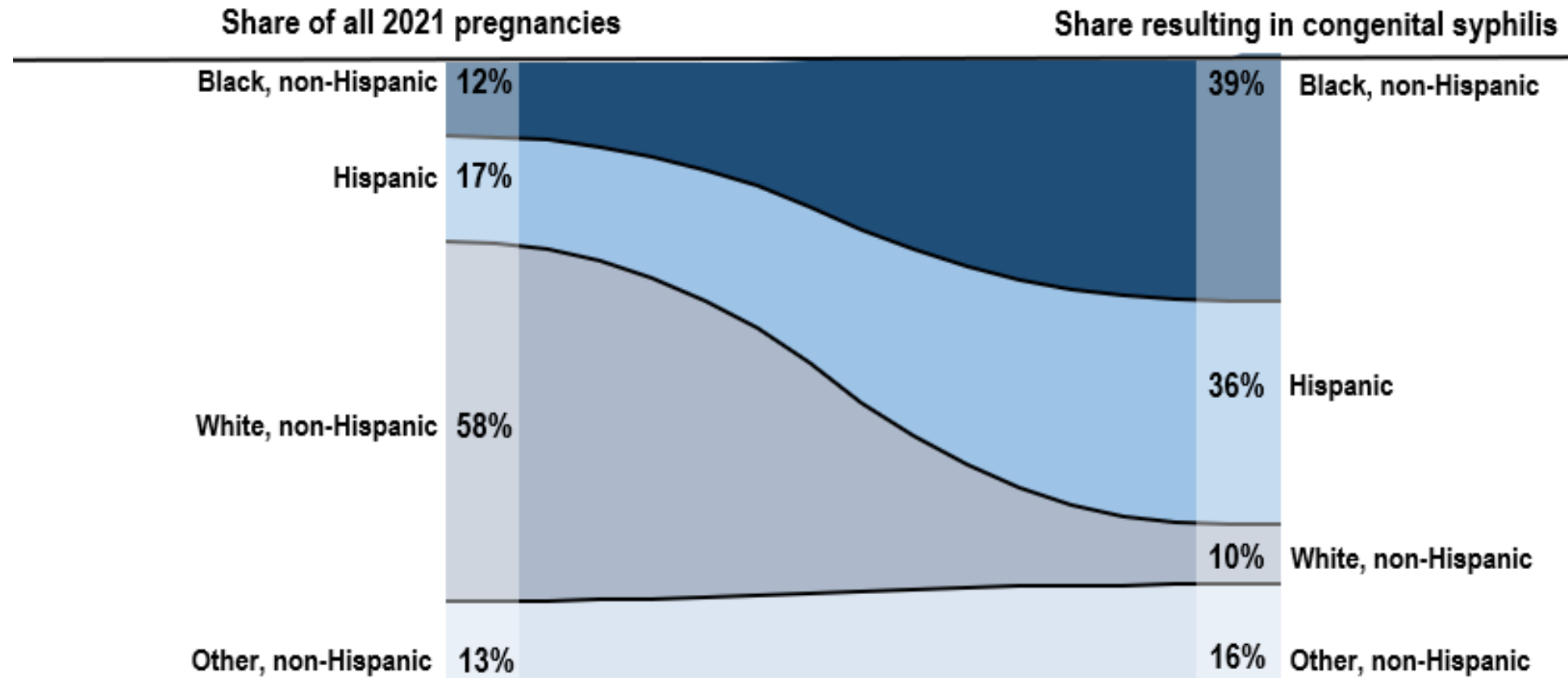
These data include all New York State, including New York City.

## Congenital syphilis is on the rise in New York State as well and has resulted in ten **stillbirths** since 2013.

2022 accounted for >20% of the total **congenital syphilis** cases reported over the past ten years, with half of **syphilitic stillbirths** occurring in the past two reporting years.



# Congenital syphilis pregnancy outcomes in New York State disproportionately impact persons identifying as Black, non-Hispanic and Hispanic.



1. Data for all pregnancies from Vital Statistics [https://www.health.ny.gov/statistics/vital\\_statistics/2021/table29.htm#1](https://www.health.ny.gov/statistics/vital_statistics/2021/table29.htm#1)

2. Other, non-Hispanic includes Asian/Native Hawaiian/Other Pacific Islander, American Indian/Alaska Native, Multi-Race, Other, and Unknown, and where race was missing.

3. Data for 2021 only.

4. Share for all pregnancies in NYS (n = 145,021).

5. Share resulting in congenital syphilis (n = 41).





# Protect babies from **syphilis.**

Syphilis is on the rise in New York. Syphilis during pregnancy can cause serious health complications for babies, even death. Testing and treatment can save babies' lives.

health.ny.gov



# Protect babies from **syphilis.**

Untreated syphilis while pregnant can cause serious health complications for babies, even death. Testing and treatment can save babies' lives.

health.ny.gov



## Expedited Partner Treatment

# EPT

If you **test positive** for chlamydia, gonorrhea, and/or trichomoniasis, **get treatment.** And ask your health care provider about **Expedited Partner Treatment (EPT) for your sex partner(s).** With EPT, providers can give medication or a prescription to you to give to your partner(s) for treatment.

health.ny.gov/EPT



## Expedited Partner Treatment

# EPT

If you **test positive** for chlamydia, gonorrhea, and/or trichomoniasis, **get treatment.** And ask your health care provider about **Expedited Partner Treatment (EPT) for your sex partner(s).** With EPT, providers can give medication or a prescription to you to give to your partner(s) for treatment.

health.ny.gov/EPT





Be **Fierce**  
Healthy sex is **empowering.**

health.ny.gov/HealthySex



Healthy sex is **part of your identity.**



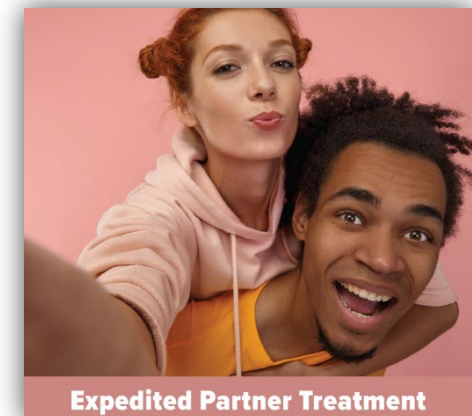
**HUMAN**

health.ny.gov/HealthySex




It's OK to talk about **SEX**

health.ny.gov/HealthySex

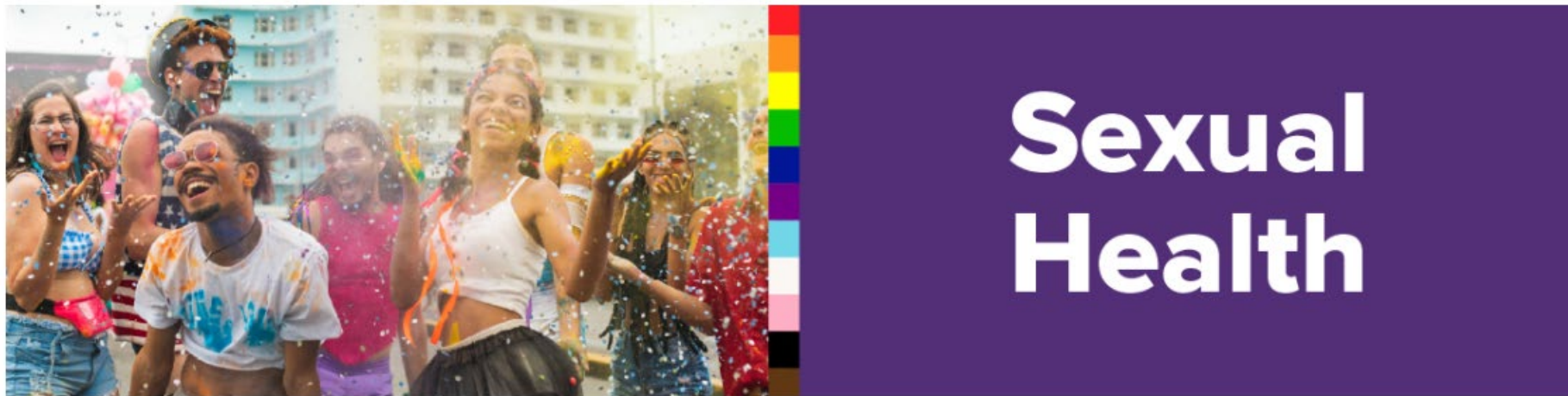



## Expedited Partner Treatment



# Thank you for your time

Please feel free to contact us with any questions: [stdc@health.ny.gov](mailto:stdc@health.ny.gov) or go to <https://campaigns.health.ny.gov/SexualHealth>



## Special thanks to:

- Emily Bruce, Shaiza Bushra, Wilson Miranda, Diane Moore, Thaddeus Price, Mike McNair, and Beth de Leon-Stevens, Office of Sexual Health and Epidemiology
  - Our partners in the Sexual Health Center for Excellence
    - All our colleagues working towards reducing sexually transmitted infections and promoting sexual health

# Clinical Update: HIV/STI Prevention

BROWN UNIVERSITY

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Associate Professor, Brown University

Chief Medical Office, Open Door Health

Consultant Medical Director, Rhode Island Department of Health



# Disclosures

**No commercial conflicts of interest.**





**Diagnose** all people with HIV as early as possible.

**Treat** people with HIV rapidly and effectively to reach sustained viral suppression.



**Prevent** new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs).

**Respond** quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.

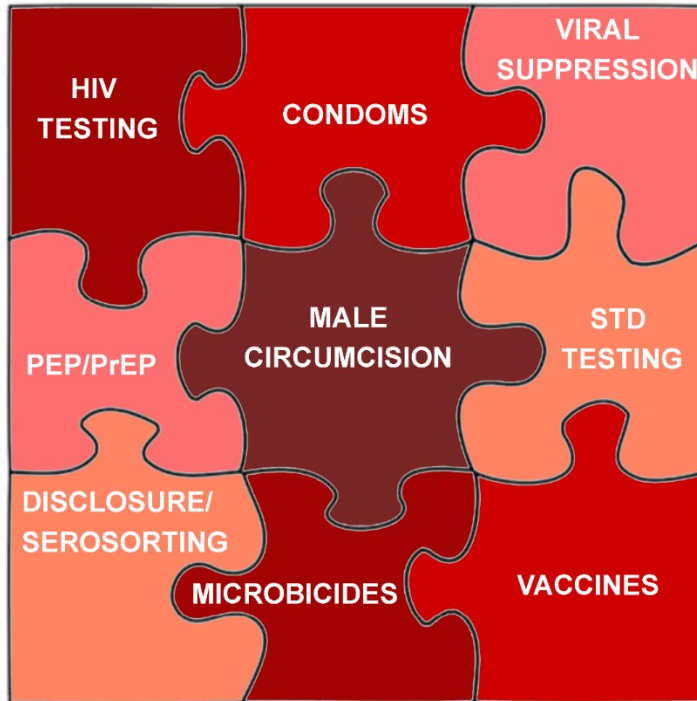


# STI Screening

## Who should I test?

### General Population (CDC/USPSTF)

- HIV at least once (CDC: 13-64 years old)
- HCV at least once (18+ years old; unless HCV prevalence <0.1%)



### Cis-gender women (CDC/USPSTF)

- Chlamydia/gonorrhea annual **opt-out** testing (24 years and younger;
- Chlamydia/gonorrhea testing if at-risk\* (25+ years)

\*Previous/current STI; new or >1 sex partner; sex partner with multiple partners, sex partner with an STI; condomless sex not in a monogamous relationship; history of incarceration; history exchanging sex for money/drugs.

\*\*Chlamydia rectal testing and gonorrhea rectal and pharyngeal testing can be considered for females based on sexual behaviors

### Men who have sex with men (CDC/USPSTF)

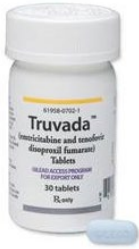
- At least annual testing for HIV, syphilis, gonorrhea (urogenital, rectal, and pharyngeal) and chlamydia\* (urogenital, rectal). Every 3-6 months if multiple risk factors.

\*Pharyngeal screening for chlamydia is not technically recommended because the clinical significance is unclear given most people are symptomatic and the prevalence is low. However, most clinics test for both.

### Transgender and Gender Diverse (CDC)

- Based on anatomy;
- Extragenital testing.

## Pre-Exposure Prophylaxis (PrEP) for HIV Prevention



### **Emtricitabine/Tenofovir Disoproxil Fumarate (Oral)**

Approved July of 2012 for HIV prevention in adolescents and adults weighing at least 35 kgs (Approved for HIV treatment in 2004).

\*Initially approved for individuals age 18+ years. In May of 2018, approved for adolescents at risk of HIV weighing at least 35 kg (Based on ATN113; enrolled adolescents ages 15-17 years).



### **Emtricitabine/Tenofovir Alafenamide (Oral)**

Approved October of 2019 for HIV prevention in adolescents and adults weighing at least 35 kgs. (Approved for HIV treatment in 2016)



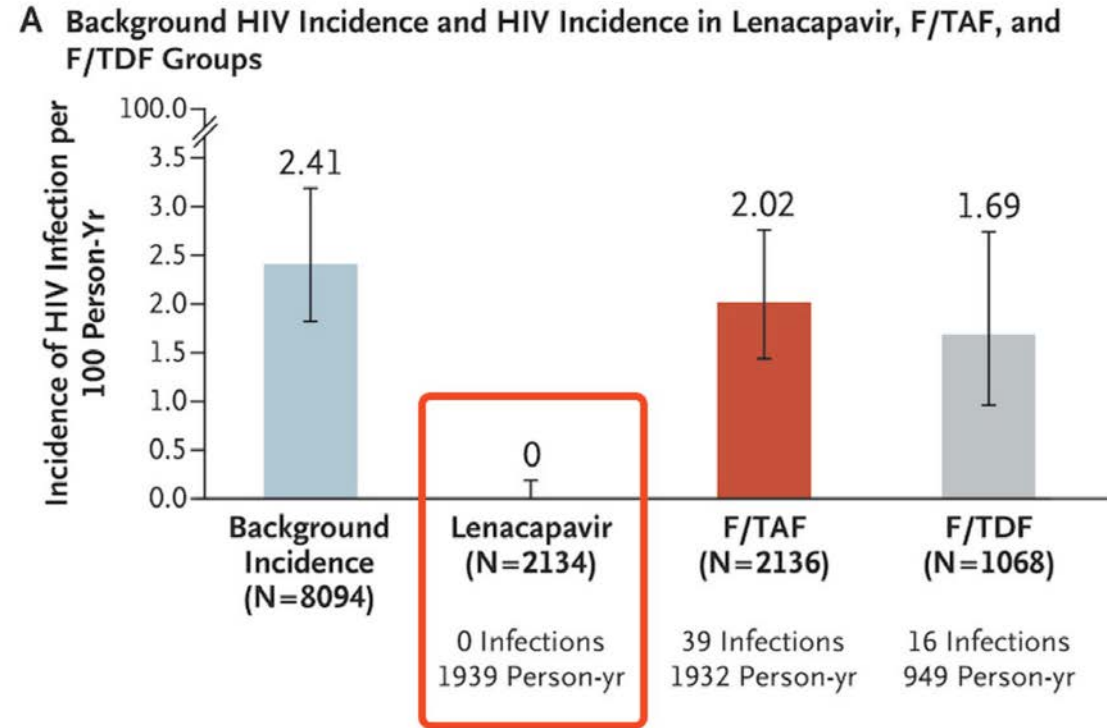
### **Cabotegravir (Injectable)**

Approved December of 2021 for HIV prevention in adolescents and adults weighing at least 35 kgs. Given first as two initial injections one month apart, then every two months.

(Approved for HIV treatment in January of 2021)

**Other “next-generation” PrEP medications are in development!**

## Lenacapavir: A Twice Yearly Injection for PrEP and HIV Prevention



\*The **PURPOSE 1** trial demonstrated that lenacapavir provided 100% protection against HIV acquisition in cisgender women. Among 5338 participants who were initially HIV-negative, 55 incident HIV infections were observed: 0 infections among 2134 participants in the lenacapavir group, 39 infections among 2136 participants in the F/TAF group, and 16 infections among 1068 participants in the F/TDF group. A second study in predominantly MSM (**PURPOSE-2**) is ongoing with results expected in the next six months.





Final Recommendation Statement

## Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis

June 11, 2019

Population	Recommendation	Grade
Persons at high risk of HIV acquisition	The USPSTF recommends that clinicians offer preexposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition. See the Clinical Considerations section for information about identification of persons at high risk and selection of effective antiretroviral therapy.	<b>A</b>



US Public Health Service

### PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES – 2017 UPDATE

A CLINICAL PRACTICE GUIDELINE



**CDC Recommendations: Inform ALL  
sexually active adults and adolescents  
about PrEP**

Providers should offer PrEP to anyone who asks for it, even if **no specific risk factors** are reported

Telling all sexually active adults and adolescents about PrEP will increase the number of people who **know about PrEP**



## **HIV-1 Incidence, Adherence, and Drug Resistance in Individuals Taking Daily Emtricitabine/Tenofovir Disoproxil Fumarate for HIV-1 Pre-Exposure Prophylaxis: Pooled Analysis From 72 Global Studies**

(Landovitz et al., Clinical Infectious Diseases, 2024)

- Among **17,274 participants**, there were **101 cases** with new HIV-1 diagnosis.
- In 54 cases with tenofovir concentration data from DBS, 45 (83.3%), 2 (3.7%), 6 (11.1%), and 1 (1.9%) had average adherence of <2, 2-3, 4-6, and  $\geq 7$  doses/week, respectively, and the corresponding incidence was 3.9 (95% CI 2.9-5.3), 0.24 (0.060-0.95), 0.27 (0.12-0.60), and 0.054 (0.008-0.38) per 100 person-years.
- In 78 cases with resistance data, 18 (23%) had M184I or V, one (1.3%) had **K65R**, and three (3.8%) had **both** mutations.
- Adherence was low in younger participants, Hispanic/Latinx and Black participants, cisgender women, and transgender women.
- Bone and renal adverse event incidence rates were 0.69 and 11.8 per 100 person-years, respectively, consistent with previous reports.

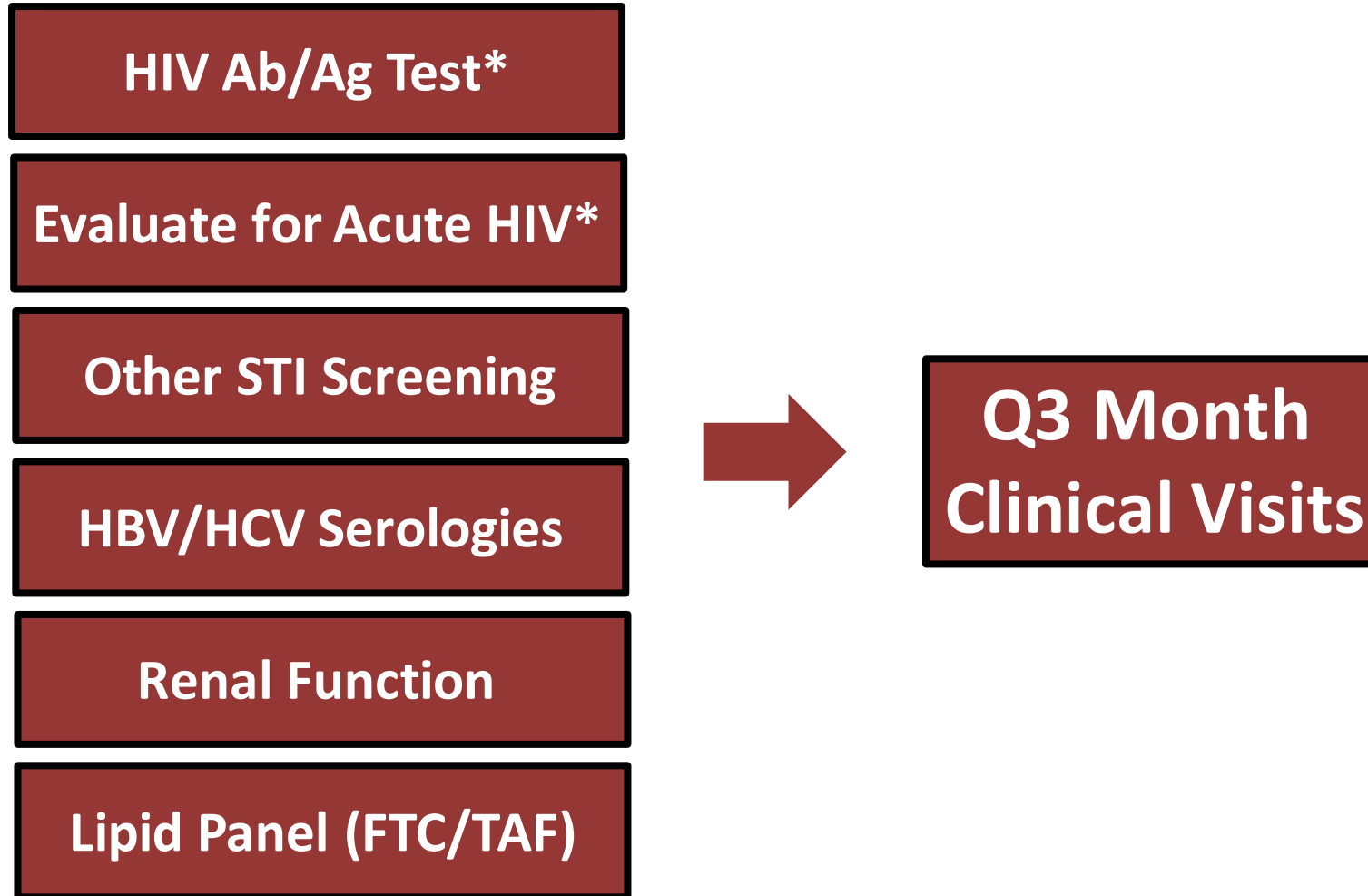
**Clinical experience has demonstrated that HIV infection while adherent to PrEP is rare!**



	<b>FTC/TDF</b>	<b>FTC/TAF</b>
<b>Risk Populations</b>	MSM, MSW, WSM, Other genders, PWID	MSM and Transgender women only
<b>Dosing</b>	Daily, intermittent/event-driven	Daily only
<b>Formulation</b>	Brand Name and Generic	Brand Name only
<b>Side Effects</b>	GI, headache, renal dysfunction, BMD	Less renal dysfunction, BMD (Clinical Relevance?)
<b>Creatinine</b>	$\geq 60$ ml/min	$\geq 30$ ml/min
<b>Metabolic</b>	None	Increased weight gain, LDL



## Initial PrEP Clinical Visit (Oral PrEP)



## PrEP Follow-up Visits

**HIV Ab/Ag and/or Viral Load**  
(Every 3 months)

**Other STI Screening**  
MSM/TGW (3 months)  
Heterosexual (6-12 months)

**Renal Function**  
≥50 years or CrCl <90mL/min (6 months)  
<50 years or CrCl ≥90ml/min (12 months)

**Lipid Panel, Weight**  
FTC/TAF only (12 months)

**Risk Reduction and Adherence Counseling**



## PrEP Clinical Visits (Injectable PrEP)

HIV Ab/Ag Test

HIV-1 RNA (Viral Load)

Other STI Screening

HBV Serologies

Renal Function

Lipid Panel (FTC/TAF)

Oral lead-in period is “optional”  
Dose: 600mg IM in the gluteal muscle  
Baseline intramuscular (IM) injection  
Second IM injection at 1 month  
Subsequent IM injections every 2 months  
HIV Ag/Ab and HIV RNA every 2 months

HPTN 083 (>4500 MSM ND TGW): 66%  
reduction in risk of HIV infection  
compared to TDF/FTC (largely due to  
improved adherence).

HPTN 084 (>3200 cisgender women): 88%  
reduction in risk of HIV infection  
compared to TDF/FTC.



## Implementation of Cabotegravir as PrEP for HIV Prevention

### Major Challenges: Cost

Truvada  
\$1100 per  
month

Descovy  
\$1700 per  
month

Generic  
TDF/FTC \$40  
per month

Apertude  
\$3700 per  
dose

- **Out-of-pocket costs:** Clinical visits, laboratory costs, medication.
- “Pharmacy benefit” versus “Medical benefit”.





## Doxycycline as Post-Exposure Prophylaxis (PEP) to Prevent Bacterial STIs (Syphilis, Gonorrhea, and Chlamydia)

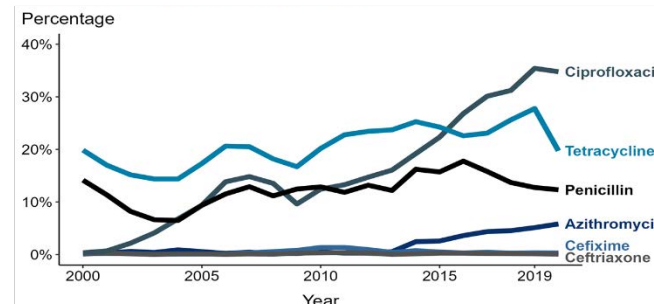
### Rationale

- STIs have been significantly increasing;
- Doxycycline has been used for longer-term prophylaxis and treatment in other settings (i.e., malaria, acne, Lyme disease, etc.);
- Generally well-tolerated;
- Low-cost.

### Doxycycline

- First-line treatment for chlamydia;
- Second-line treatment for syphilis;
- Some efficacy against gonorrhea.

*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), 2000–2020



\* Resistance: Ciprofloxacin: MIC  $\geq 1.0$   $\mu\text{g}/\text{mL}$ ; Penicillin: MIC  $\geq 2.0$   $\mu\text{g}/\text{mL}$  or Beta-lactamase positive; Tetracycline: MIC  $\geq 2.0$   $\mu\text{g}/\text{mL}$

† Elevated MICs: Azithromycin: MIC  $\geq 1.0$   $\mu\text{g}/\text{mL}$  29 (2000–2004);  $\geq 2.0$   $\mu\text{g}/\text{mL}$  (2005–2020); Ceftriaxone: MIC  $\geq 0.125$   $\mu\text{g}/\text{mL}$ ; Cefixime: MIC  $\geq 0.25$   $\mu\text{g}/\text{mL}$





## Doxycycline

### Doxycycline as Post-Exposure Prophylaxis (PEP) to Prevent Bacterial STIs (Syphilis, Gonorrhea, and Chlamydia)

- First approved by the FDA in the United States in 1967
- A tetracycline which binds to the 30S ribosomal subunit and blocks protein synthesis of the bacteria (bacteriostatic)
- >90% of oral doxycycline is absorbed
- Crosses the blood-brain barrier and the placenta
- Generally avoided in pregnancy due to concern of teeth discoloration and bone development.
- Broad-spectrum activity against Gram-positive, Gram-negative, atypical bacteria, rickettsia, etc.
- Chelates divalent/trivalent cations (i.e., avoid calcium, iron, aluminum, and magnesium; decreased absorption)
- Drug interactions: Multivitamins, warfarin, methotrexate, carbamazepine, fosphenytoin, other medications. Not oral contraceptives.



### **ANRS IPERGAY**

(France; Molina et al., 2017, *Lancet*)

Open-label, randomized study 1:1 of 200mg doxycycline PEP within 24 hours after sex (and no later than 72 hours) versus no prophylaxis among N=232 MSM and TGW. Primary outcome: Occurrence of a first STI.

Overall 47% reduction of a first STI in PEP group. A 70% reduction in Chlamydia; 73% in Syphilis; Gonorrhea not significant.

### **DoxyPEP**

(USA; Luetkemeyer et al., 2023, *NEJM*)

Open-label, randomized study 1:1 of 200mg doxycycline PEP within 24 hours after sex (and no later than 72 hours) versus no prophylaxis among N=501 MSM and TGW. Primary outcome: At least one incident STI during follow-up.

Overall 65% reduction in STI incidence/quarter; Reductions in Chlamydia (74-88%), Syphilis (77-87%), Gonorrhea (55-57%).

### **DOXYVAC**

(France; Molina et al., 2024, *Lancet ID*)

Prospective, randomized study of four groups including doxycycline as PEP, Men B vaccine, both, or neither among N=566 MSM. Primary outcome: Occurrence of a first STI.

Overall reductions in chlamydia (86%\*), syphilis (79%\*), and gonorrhea (33%\*) for PEP; MenB with 22% reduction in gonorrhea (not significant).

### **dPEP-Kenya**

(Kenya; Stewart et al., 2023, *NEJM*)

Open-label, randomized study 1:1 of 200mg doxycycline PEP within 24 hours after sex (and no later than 72 hours) versus no prophylaxis among N=449 cisgender heterosexual women. Primary outcome: Incident STI over 12 months follow-up.

No significant differences (N=50 STIs PEP compared to N=59 control). Lack of adherence (Stewart et al., ISSTD, 2023). Similar to HIV PrEP initially.





## Safety of longer-term doxycycline use: A systematic review and meta-analysis with implications for bacterial STI chemoprophylaxis

### Background

The goal of the study was to evaluate the safety of longer-term doxycycline use (defined as eight or more weeks) in the context of potential use as STI chemoprophylaxis through a systematic literature review and meta-analysis.

### Results

A total of 67 studies were included in the systematic review. Most common adverse events included gastrointestinal symptoms (i.e., nausea, vomiting, and abdominal pain), dermatologic (i.e., rash), and neurological (i.e., headache and dizziness) symptoms. Discontinuation of doxycycline due to adverse events was relatively uncommon in most studies. A meta-analysis of placebo controlled clinical trials (N=18) revealed gastrointestinal and dermatological adverse events were more likely to occur in the doxycycline group.

### Conclusion

Longer-term (8+ weeks) doxycycline use is generally safe and may be associated with minor side-effects.

Relative risk of adverse events between doxycycline and placebo arms of randomized controlled trials

Outcome	κ	Relative risk (95% CI)	I <sup>2</sup> %	P-value
<i>All included studies</i>				
Any AE	9	1.03 (0.89, 1.21)	59.6	0.66
Severe AE	12	0.83 (0.59, 1.16)	2.20	0.28
Neurological AE	11	0.88 (0.73, 1.05)	0.90	0.15
Gastrointestinal AE	12	1.68 (1.19, 2.38)	72.2	<0.01
Dermatological AE	9	3.55 (1.39, 9.01)	45.9	0.01
Dropped due to AE	18	1.62 (1.12, 2.34)	7.50	0.01

κ = number of studies; AE = adverse event; I<sup>2</sup> variation across studies because of heterogeneity rather than chance; CI = confidence interval





**Doxycycline  
Hyclate**



**Doxycycline  
Monohydrate**

- Generally considered the same
- Refers to what salt is attached to the active drug molecule
- The salt molecule is inactive but can affect absorption
- Doxycycline monohydrate is less soluble and may have less gastrointestinal side-effects
- Doxycycline hyclate fully dissolves in water, doxycycline monohydrate only slightly dissolves
- Doxycycline monohydrate may be cheaper



## Implementation and Unanswered Questions: Doxycycline as PEP

**Do people actually want to take it?**

**Multiple studies demonstrate the willingness of MSM to use doxycycline as PEP (and also as PrEP).**

**How do we achieve major goals of STI control?**

**Major goals include reducing the overall number of bacterial STI cases and reducing associated sequelae and complications of STIs.**

**How to effectively reach people?**

**Specialty clinics (HIV, STI clinics), FQHCs, primary care clinics, community-based clinics, etc.**

**How to address disparities?**

**How do we effectively reach African American/Black and Hispanic/Latinx communities?**





## Implementation and Unanswered Questions: Doxycycline as PEP

**What about cis-gender women?**

**The dPEP-Kenyan study did not show efficacy in cis-gender women. Low adherence may have been the issue.**

**Impact on antimicrobial resistance?**

**Will we see increasing rates of doxycycline resistance in STIs? Doxycycline resistance in *T. pallidum* and *C. trachomatis* is rare. What about *M. genitalium*? *N. gonorrhoeae*? Selection of tetracycline resistance may influence multi-drug resistance in *N. gonorrhoeae* (Mortimer et al., ISSTD).**

**Will we see increasing rates of doxycycline resistance in other bacteria? (i.e., community-acquired MRSA, etc.)**

**Impact on the microbiome?**

**Will doxycycline as PEP affect the microbiome including metabolic changes?**





## Doxycycline as PEP: Conclusions

**What does the evidence show?**

**Doxycycline 200mg orally within 24 and up to 72 hours of condomless oral, vaginal or anal sex in MSM/TGW reduces infection with bacterial STIs.**

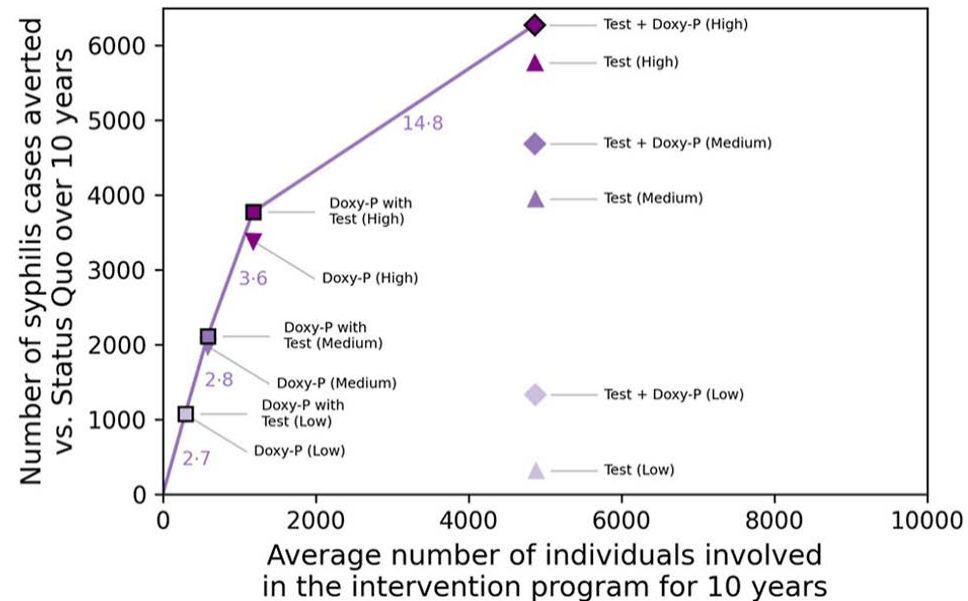
**Current CDC Recommendation**

**CDC recommends that MSM and TGW who have had a bacterial STI (specifically syphilis, chlamydia, or gonorrhea) diagnosed in the past 12 months should receive counseling that doxyPEP can be used as PEP to prevent these infections. Following shared decision-making with their provider, this group can receive a prescription for doxyPEP to be self-administered within 72 hours after having oral, vaginal, or anal sex. Persons who are prescribed doxyPEP should undergo STI testing at baseline and every 3–6 months thereafter. Ongoing need for doxyPEP should be assessed every 3 to 6 months as well.**





## Impact of screening and doxycycline prevention on the syphilis epidemic among men who have sex with men in British Columbia: a mathematical modelling study (Lancet Regional Health, 2024)



**“Under the combined interventions (i.e., syphilis screening and DoxyPEP), the syphilis incidence rate could be as low as 0.0 (0.0-0.1) and 0.8 (0.3–1.8) per 1,000 PYs, respectively.”**



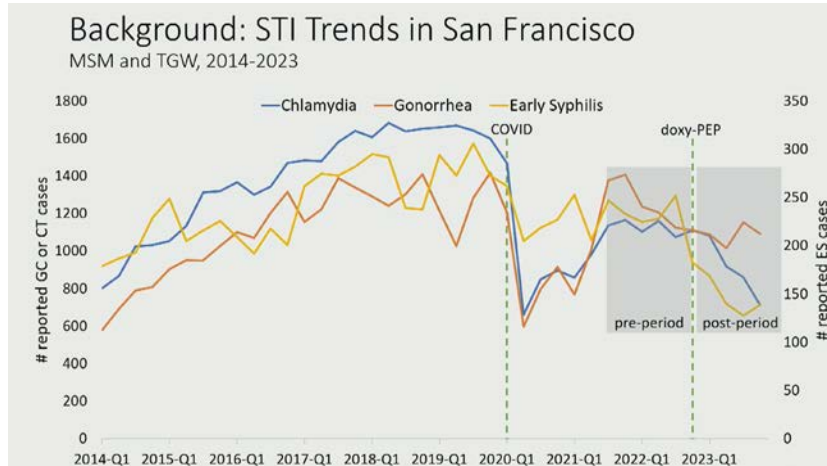
Oral Abstract Session-04  
Monday, March 4, 2024

## Doxy-PEP Associated With Declines in Chlamydia and Syphilis in MSM and Trans Women in San Francisco

Madeline Sankaran  
San Francisco Department of Public Health, San Francisco, CA, USA

*Disclosure: Ms Sankaran reported no relevant financial relationships with ineligible companies.*

CROI 2024



### Background: Doxy-PEP Uptake at 3 SF Clinics

- 3 SF clinics provide sentinel surveillance data on uptake
- Rapid adoption of doxy-PEP
  - ~600 starts in first 2 months
- Starts through 2023:
  - >3,700
  - 20% of MSM and TGW

Quarterly Doxy-PEP Starts at 3 SF Clinics

Quarter	# of Starts
2022 Q4	576
2023 Q1	1245
2023 Q2	765
2023 Q3	702
2023 Q4	491

GETTING TO ZERO SAN FRANCISCO

CROI 2024

### Methods

- Interrupted time series analysis – **ecologic test of association**
  - Monthly case counts among MSM and TGW from citywide surveillance data
  - Chlamydia, gonorrhea, and early syphilis
  - Pre-period: Jul 1, 2021 - Oct 31, 2022
  - Post-period: Nov 1, 2022 – Nov 30, 2023
  - Supplemental analysis of chlamydia among cis women
- Autoregressive integrated moving average (ARIMA) models to predict post-period incidence in the absence of doxy-PEP
- Compared model predictions to observed trends in the post-period

Schaffer et al, BMC Medical Research Methodology 2021; 21:58

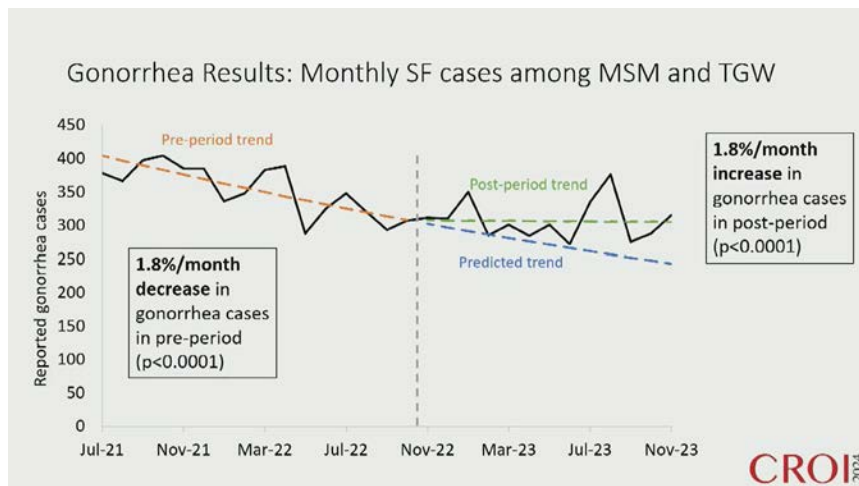
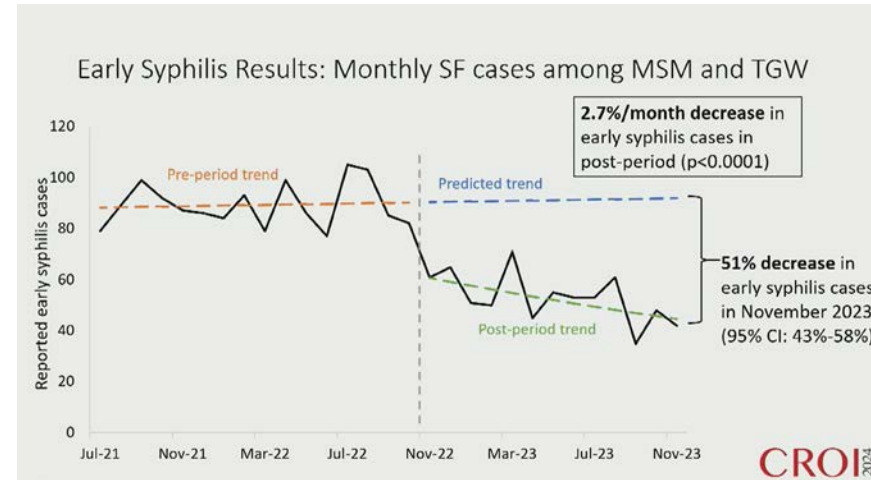
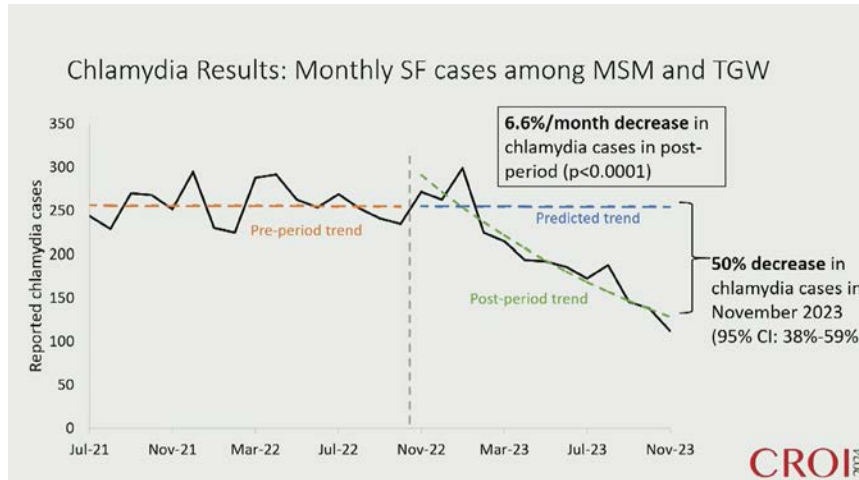
CROI 2024

October 2022: SFDPH released [guidelines](#) for doxy-PEP use

- Recommend** doxy-PEP to cis men and trans women who in the past year:
  - had a bacterial STI, and
  - reported condomless anal or oral sex with at least 1 cis man or trans woman
- Offer** to broader population of cis men and trans women with multiple partners but no bacterial STI in the past year



# Doxycycline as Post-Exposure Prophylaxis (PEP) to Prevent Bacterial STIs



### Conclusions and Next Steps

- **Implementation of doxy-PEP guidelines was associated with significant decreases in chlamydia and early syphilis among MSM and TGW in San Francisco, but not gonorrhea**
  - Findings supported by increase in chlamydia among cis women
- Immediate decrease in early syphilis not likely due to doxy-PEP
- Lack of decline in GC warrants further investigation
- Monitor for disparities in uptake and impact in different racial/ethnic groups
- Monitor tetracycline resistance pattern in GC and impact on doxy-PEP efficacy

CROI 2024

\*Limitations: No data on adherence, ecologic associations and can't control for confounders or identify causality (changes in testing volume? Changes in sexual practices, i.e., due to mpox outbreak summer of 2022?)



# Open Door Health and DoxyPEP

Began routinely offering in November 2023

EMR Messaging, Routine Education, Standing Orders

Approximately 200 people on DoxyPEP

MSM/TGW (May to November 2023, N=314): 50% Aware, 49% Interested, 18% Used

MSM/TGW More Likely to Use DoxyPEP: History of STI ever and in the past 12 months, and those that had used HIV PrEP.



**DOXYPEP**  
LEARN MORE TODAY AT [odhpvd.org](https://odhpvd.org)



## Contact Information



**Philip A. Chan, MD, MS**

**Associate Professor of Medicine, Brown University  
Medical Director, Rhode Island Department of Health  
Chief Medical Officer, Open Door Health**

**[Philip\\_Chan@brown.edu](mailto:Philip_Chan@brown.edu)**

# Case One

A 35-year-old cisgender man who works in a restaurant comes to you as a primary care physician for his first well visit.

How and when do you approach asking about sexual health?

# Case One

The patient has no medical history, tells you that he is sexually active with men and women, and has had 10 partners in the last year with intermittent condom use.

What kind of testing or counseling should be offered?

Should the patient be offered HIV pre-exposure prophylaxis (PrEP)?

Should the patient be offered Doxycycline for post exposure prophylaxis (Doxy-PEP)?

# Case Two

A 22-year-old cisgender man comes in because he noted several “sores” over the last 1 week. He has 1 lesion on his penis, several lesions in his pubic area.

He is sexually active with cisgender men. He has had 5 partners in the last few months. He has been traveling to celebrate graduation from college.

# Case Two



<https://www.gov.uk/guidance/>

# Case Two

What is the differential diagnosis?

What should you do next?

# Case Two

Tests are pending and you are concerned that this could be mpox.

What isolation recommendations would be appropriate?

If the testing is positive for mpox, should tecovirimat (TPOXX) be offered?

# Case Three

A 65-year-old cisgender woman that you have been following for 20 years comes to you for her annual visit. She has been widowed for 10 years. She takes atorvastatin and warfarin for hypertension and atrial fibrillation.

Should you ask her about any sexual activity?

# Case Three

Patient states that she recently got in touch with an old friend from Facebook and they started dating. She is very happy to be social again, and they have been having sex. She says she has also recently made a dating profile. Given her age, she didn't think she needed to use condoms.

Does she need testing for STIs?

# Case Three

She has a screening antibody treponemal test that is positive.

How do you interpret this finding at this point?

How should you approach further testing for syphilis?

# Case Three

The patient's RPR comes back 1:64 and the patient denies ever having syphilis or being treated with PCN injection in the past.

How do you treat this patient?

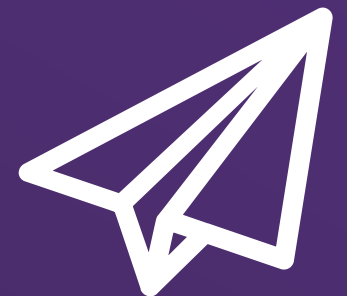
# Case Three

Should the patient be offered HIV pre-exposure prophylaxis (PrEP)?

Should the patient be offered Doxycycline for post exposure prophylaxis (Doxy-PEP)?

# Q&A

Email us your questions at [GrandRounds@health.ny.gov](mailto:GrandRounds@health.ny.gov)



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