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Doxy-PEP for STI prevention in Cisgender gbMSM and Trans Women



Jordan Goodridge, MD, CCFP
&
Devan Nambiar, MSc.

September 28, 2023

Disclosure

Presenter Disclosure – Jordan Goodridge

- I do have a relationship with not-for-profit organizations:
 - GMSH
 - CAMH (ECHO program)
 - Rainbow Health Ontario
 - Mitigating Potential Bias: The above are non-profit organizations. The educational resources are peer-reviewed and based on existing accepted guidelines and expert opinion.

Presenter Disclosure – Devan Nambiar

- I do have a relationship with not-for-profit organizations:
 - CIHR Canadian HIV Trials Network, Community Advisory Committee
 - Canadian Agency of Drugs and Technology in Health, Patient Advisory Committee

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Learning Objectives

By attending this rounds, the learner should be able to:

- Interpret research studies on the efficacy of doxycycline post-exposure prophylaxis (doxy-PEP) for sexually transmitted infection (STI) prevention
- Describe the benefits versus risks of doxy-PEP in gay, bisexual, and other men- who-have-sex-with-men (gbMSM), trans women, and people living with HIV (PLHIV)
- Discuss how to implement access and facilitate removing barriers for sexual health discussions
- Develop competencies in prescribing doxy-PEP for gbMSM, trans women, and PLHIV

WHO IS THE GMSH?

- A group of queer men working to improve the health and wellbeing of 2-Spirit, gay, bisexual, queer, and other men who have sex with men.
- Produce resources, provide training, and run campaigns on sexual health—including HIV and other STBBIs for healthcare providers and community members
- Funded by the MOH, AIDS Bureau to increase the capacity of front-line HIV services to support 2SGBTQMSM



VALUES AND APPROACH

Gay is good.

Honest & frank.

Evidence Based.

Consistent & collaborative.

Agile & adaptive.

Presentation Outline

- STI rates, HIV PrEP, and Biomedical Prevention of STIs
- Efficacy of doxycycline in STI prevention
- Concerns around prescribing doxy-PEP, including antimicrobial resistance
- Prescribing details of doxy-PEP, when indicated
- Case scenario
- Q & A

Burden of STI rates in Ontario

2021 Chlamydia Data at a Glance

35,389 cases

Rate: 238.7 per 100,000

2021 Gonorrhoea Data at a Glance

9,814 cases

Rate: 66.2 per 100,000

2021 Syphilis, infectious Data at a Glance

2,946 cases

Rate: 19.9 per 100,000

Doxycycline

- Inexpensive antibiotic
- Class: tetracycline antibiotics
- Common uses include: treatment of acne, malaria, bacterial

Poll 1

- Doxycycline post-exposure prophylaxis (PEP) reduces bacterial STIs in gbMSM and transgender women, including people living with HIV.
True False

Poll 2

- Doxycycline post-exposure prophylaxis reduces bacterial STIs in cisgender women. True False

Review of studies on Doxy-PEP for STIs

First author, year of pub.	Sample size	Study population	Intervention	Duration
Molina, 2018 (ANRS IPERGAY)	232	MSM & transwomen without HIV, on HIV PrEP	Doxy-PEP	Median follow-up: 8.7 mos
Luetkemeyer, 2023 (DoxyPEP)	780	MSM LHIV & MSM on HIV PrEP	Doxy-PEP	12 mos
Molina, prelim data 2023	700	MSM already enrolled ANRS PREVENIR PrEP Trial	Doxy-PEP	18 mos



State of California—Health and Human Services Agency
California Department of Public Health



April 28, 2023

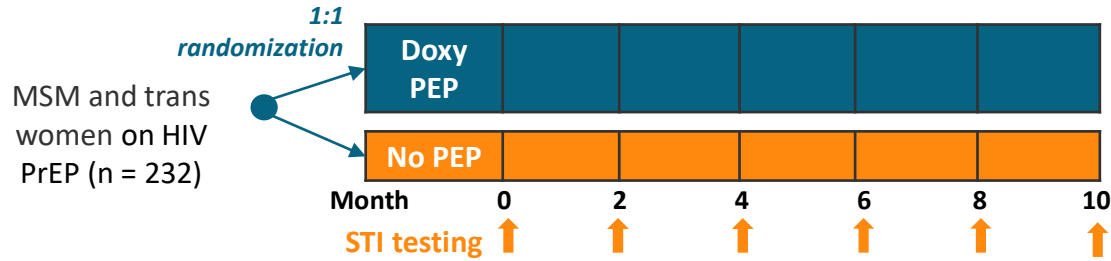
“CDPH recommends the following:

1. **Recommend doxy-PEP** to men who have sex with men (MSM) or transgender women (TGW) who have had ≥ 1 bacterial STI in the past 12 months.
2. **Offer doxy-PEP using shared decision-making** to all non-pregnant individuals at increased risk for bacterial STIs and to those requesting doxy-PEP, even if these individuals have not been previously diagnosed with an STI or have not disclosed their risk status.
3. **Provide comprehensive preventative sexual health counseling and education** to all sexually-active individuals to include HIV/STI screening, doxy-PEP, HIV pre-exposure prophylaxis (PrEP)/HIV post-exposure prophylaxis (PEP), vaccinations... expedited partner therapy, and/or contraception where warranted.”

Doxycycline PEP Efficacy

Doxy-PEP in ANRS IPERGAY study

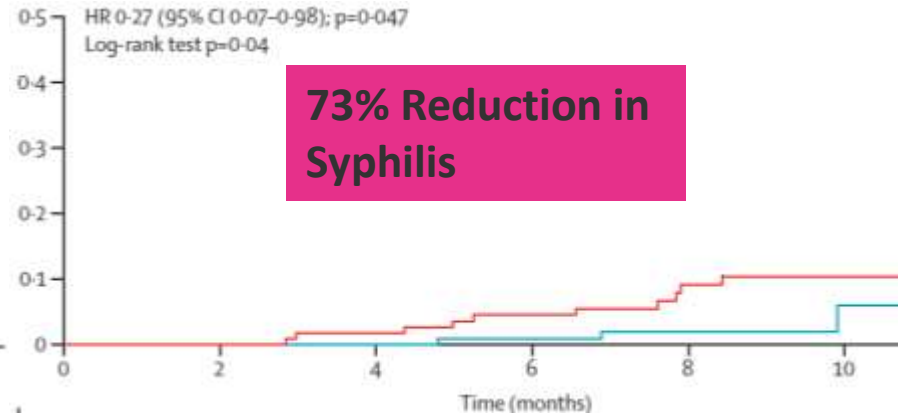
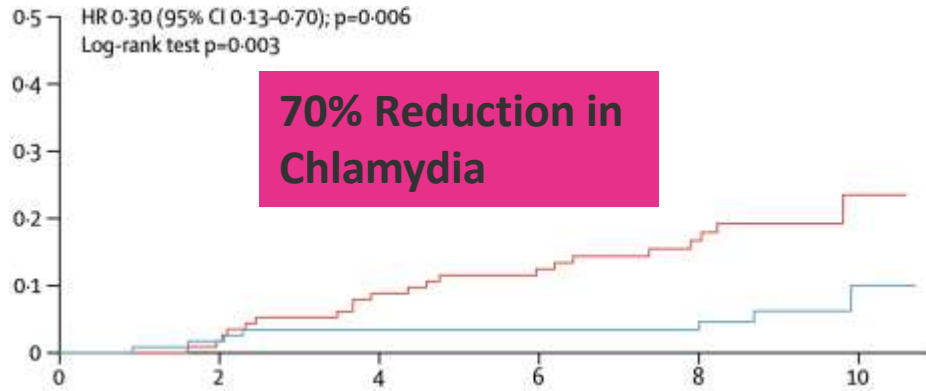
- Sub-study of doxyPEP in **ANRS IPERGAY PrEP**, at French sites



DoxyPEP: single oral dose of 200 mg doxycycline within 24 hrs after sex

- Primary endpoint: occurrence of a first STI (gonorrhoea, chlamydia, or syphilis) during the 10-month follow-up

Doxy-PEP in ANRS IPERGAY study (cont'd)



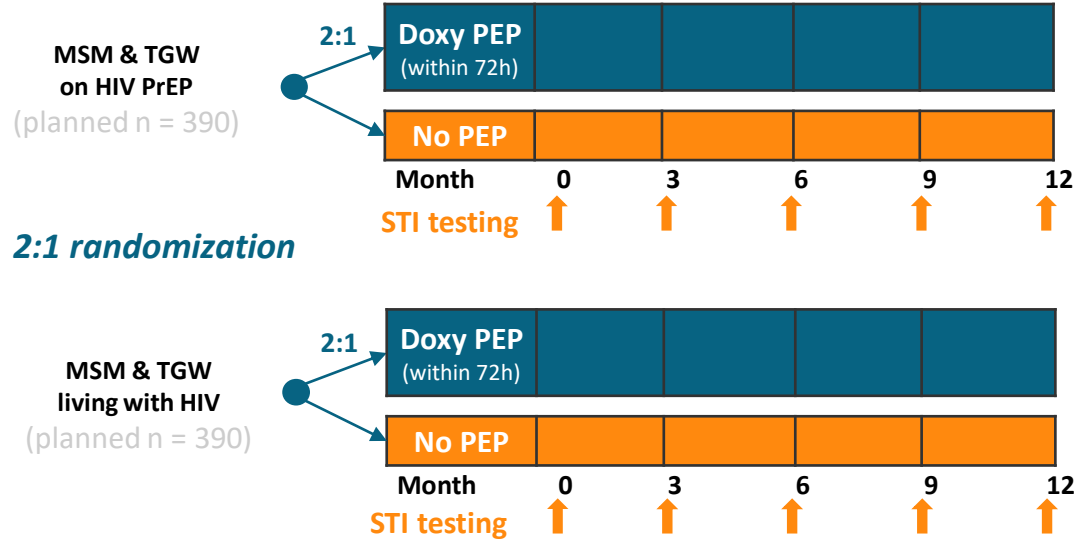
- Gonorrhoea infection: *trend* in decreased rate (HR 0.83), but ***not statistically significant***
 - High rates of tetracycline resistance in France (56% at time of study)
 - 7/9 positive gonorrhoea cultures detected tetracycline resistance (*more on this later*)

DoxyPEP Study to Prevent Bacterial STIs

- Randomized open-label trial (n=501) among MSM/TGW in Seattle and San Francisco

Inclusion criteria:

- Male sex at birth, living with HIV or on HIV PrEP
- ≥ 1 STI in past 12 mos
- Condomless sex with ≥ 1 male partner in past 12 mos

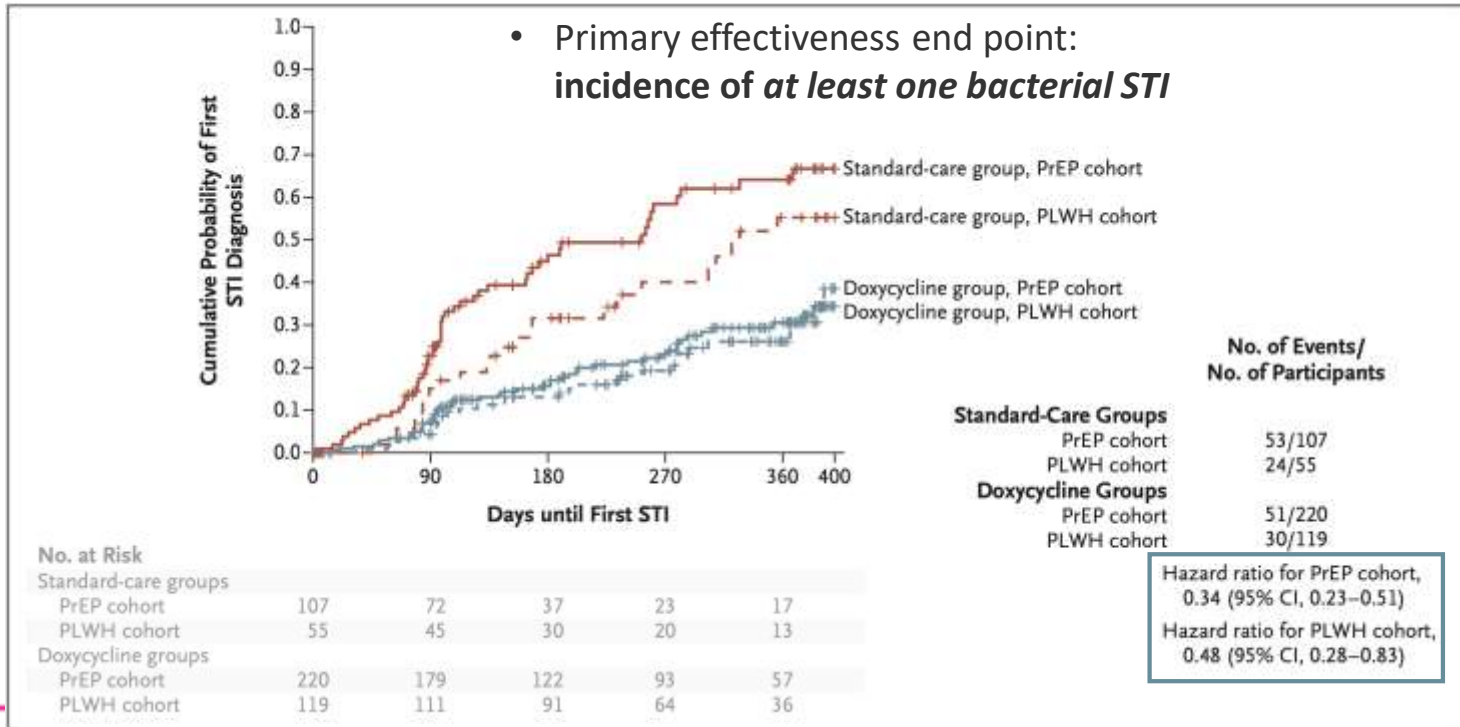


Luetkemeyer AF, et al. Postexposure Doxycycline to Prevent Bacterial Sexually Transmitted Infections. *N. England J. Med*, 2023, 388:1296-1306.

doi: 10.1056/NEJMoa2211934

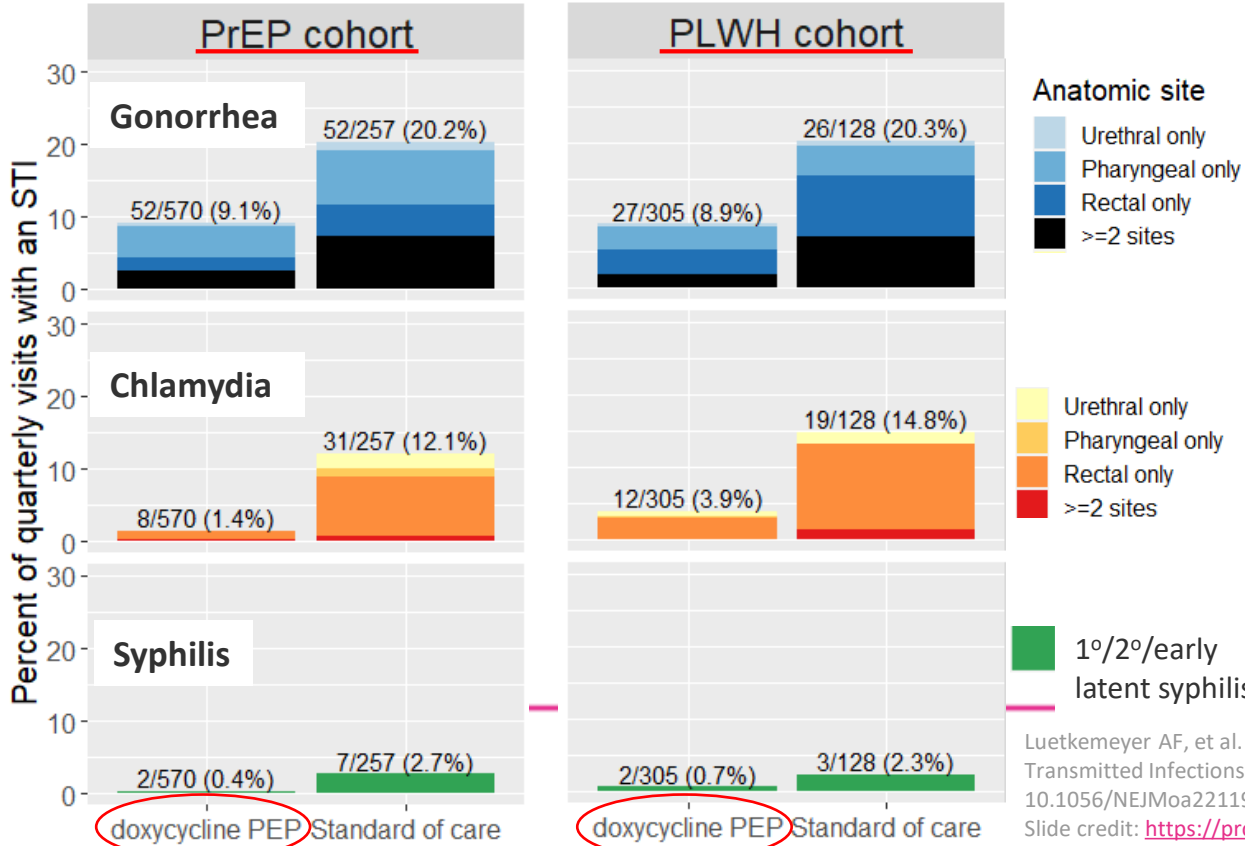
Slide credit: <https://programme.aids2022.org/Abstract/Abstract/?abstractid=13231>

DoxyPEP Study to Prevent Bacterial STIs



Luetkemeyer AF, et al. Postexposure Doxycycline to Prevent Bacterial Sexually Transmitted Infections. *N. England J. Med*, 2023, 388:1296-1306. doi: 10.1056/NEJMoa2211934

DoxyPEP Study to Prevent Bacterial STIs



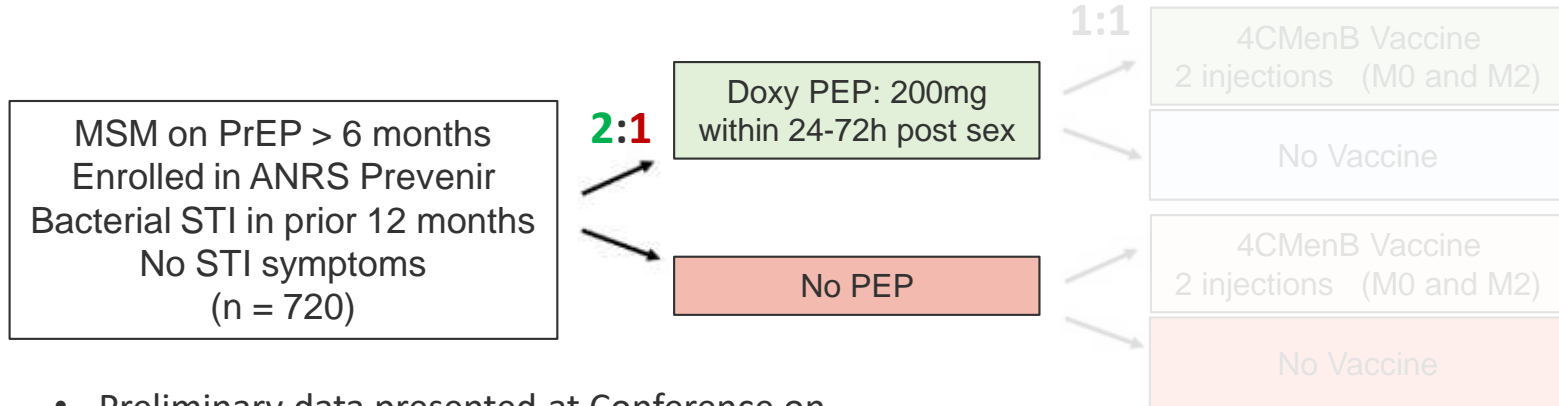
Reduction in each STI per quarter		
Relative risk (95% CI)		
	PrEP	PLWH
GC	0.45 = 55% reduction (0.32 - 0.65) <i>p</i> <0.0001	0.43 = 57% reduction (0.26 - 0.71) <i>p</i> =0.001
CT	0.12 = 88% reduction (0.05 - 0.25) <i>p</i> <0.0001	0.26 = 74% reduction (0.12 - 0.57) <i>p</i> =0.0007
Syphilis	0.13 = 87% reduction (0.03 - 0.59) <i>p</i> =0.0084	0.23 = 77% reduction (0.04 - 1.29) <i>p</i> =0.095

Luetkemeyer AF, et al. Postexposure Doxycycline to Prevent Bacterially Transmitted Infections. *N. England J. Med.*, 2023, 388:1296-1306. doi: 10.1056/NEJMoa2211934

Slide credit: <https://programme.aids2022.org/Abstract/Abstract/?abstractid=13231>

DOXYVAC Trial (Ongoing)

- Estimated study completion date: Sep 2023

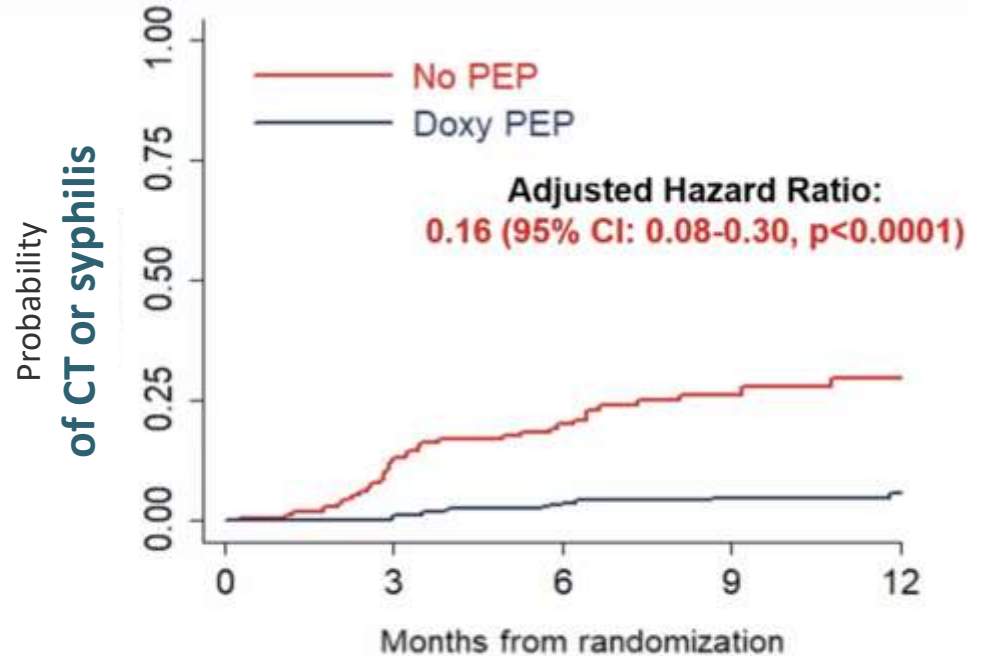


- Preliminary data presented at Conference on Retroviruses and Opportunistic Infections (Feb 2023)
- Primary endpoint: probability of CT or syphilis infxn

DOXYVAC Trial

Median follow-up: 9 months
(IQR: 6 to 12)

49 subjected infected
36 in No PEP arm
(incidence 35.4/100 PY),
13 in Doxy PEP arm
(incidence 5.6/100 PY)



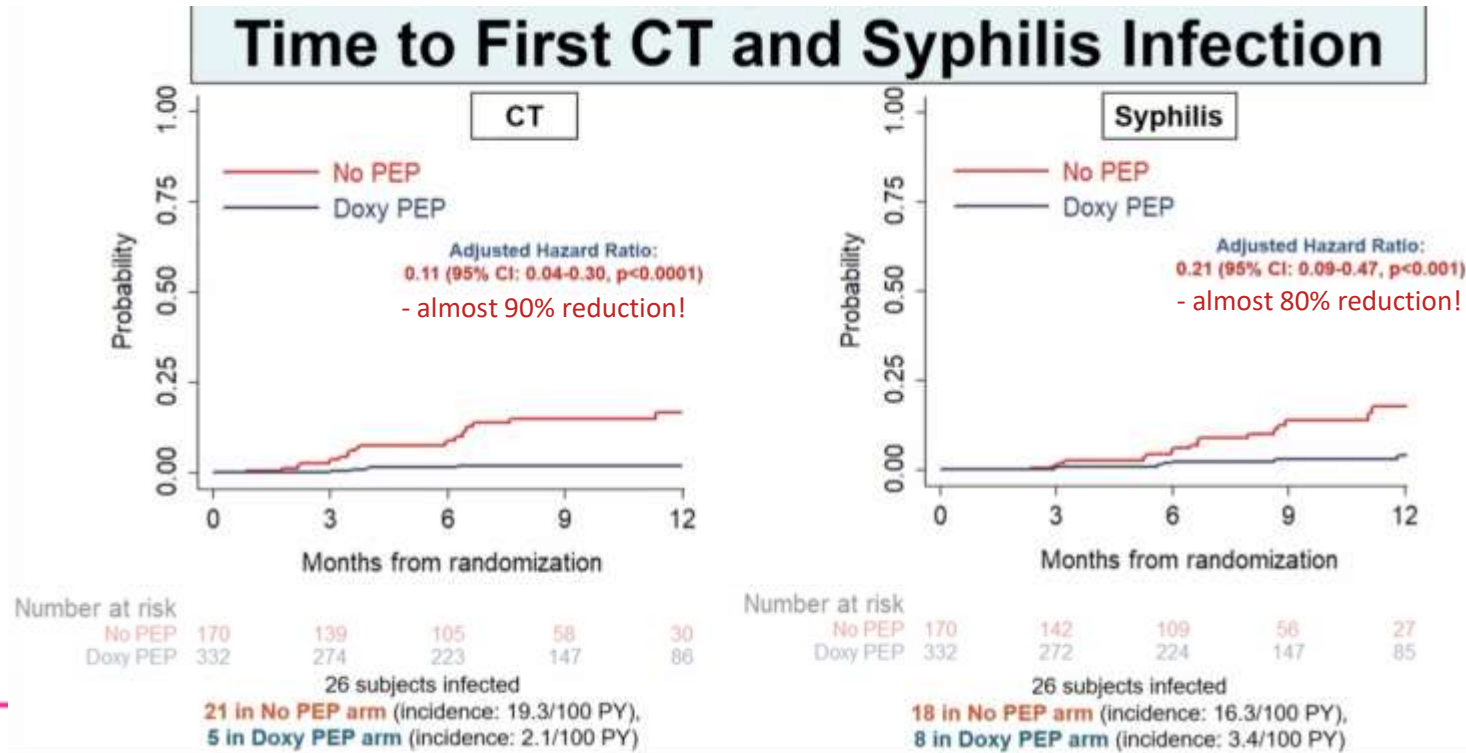
Number at risk

No PEP	170	137	99	47	22
Doxy PEP	332	271	220	144	83

Molina et al. 2023. ANRS 174 DOXYVAC: An open-label randomized trial to prevent STIs in MSM on PrEP. Available from:

<https://www.croiconference.org/abstract/anrs-174-doxyvac-an-open-label-randomized-trial-to-prevent-stis-in-msm-on-prep/>

DOXYVAC Trial

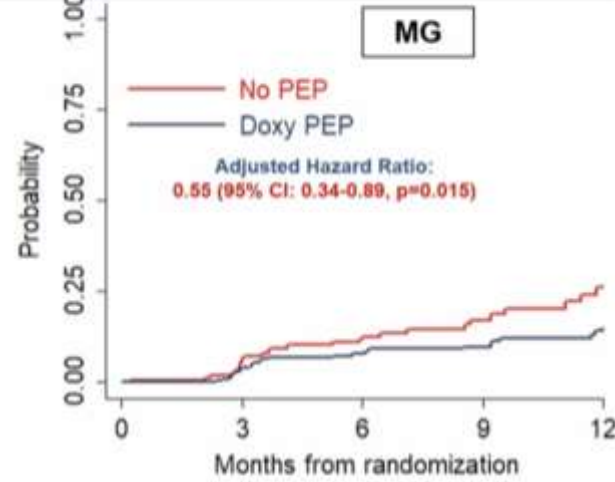
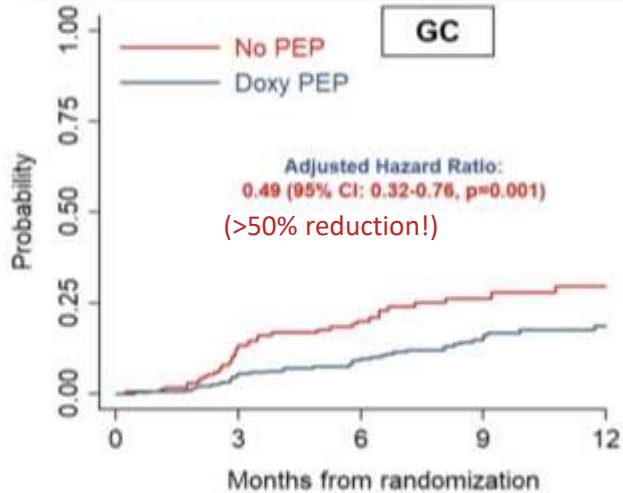


Molina et al. 2023. ANRS 174 DOXYVAC: An open-label randomized trial to prevent STIs in MSM on PrEP. Available from:

<https://www.croiconference.org/abstract/anrs-174-doxyvac-an-open-label-randomized-trial-to-prevent-stis-in-msm-on-prep/>

DOXYVAC Trial

Time to First GC and MG infection



MG =
mycoplasma
genitalium

Number at risk

No PEP	170	125	90	47	20
Doxy PEP	332	259	201	128	68

84 subjects infected
40 in No PEP arm (incidence: 41.3/100 PY),
44 in Doxy PEP arm (incidence: 20.5/100 PY)

Number at risk

No PEP	170	148	110	67	38
Doxy PEP	332	298	234	157	89

68 subjects infected
31 in No PEP arm (incidence: 29.4/100 PY),
37 in Doxy PEP arm (incidence: 16.8/100 PY)

Doxy PEP's lack of efficacy in cisgender women

- Doxy PEP did not reduce the risk for STIs (chlamydia or gonorrhea) among African cisgender women in the dPEP Kenya trial (n=449) (not yet published)
- **Antibiotic resistance** provides an explanation for why gonorrhea wasn't prevented, but it doesn't explain why chlamydia wasn't prevented
- Other reasons cited:
 - **Suboptimal adherence**
 - Barriers for some women: social harms, verbal and physical violence if taking doxy PEP
 - Frequency and timing of doxycycline being evaluated further
 - Anatomy differences?

[DoxyPEP STI Prevention Works Well for Gay Men—But Not For Women – POZ](#)

[Doxycycline does not prevent STIs among cisgender women \(newswise.com\)](#)

Doxy PEP:

Dosage, side effects and contraindications

- 200 mg after unprotected sex (oral, anal, vaginal) ideally within 24 hrs (no later than 72 hrs)
 - If sexually active again within 24 hours, repeat dose (200mg) at 24 hours
 - Side effects:
 - photosensitivity (wear sunscreen)
 - upset stomach
 - (less common) esophageal irritation
 - Do not lie down for 30 mins after taking doxy to reduce acid reflux and irritation to throat
 - Contraindications:
 - Do not take if pregnant
 - Avoid taking within 2 hours of dairy intake, calcium, antacids, multivitamins
-

Poll 3

- In the last year, have your patients requested a prescription for doxycycline for STI prevention? Yes No

Poll 4

- Have you prescribed doxycycline PEP to your clients/patients?
Yes No

Poll 5

- Are you concerned about drug resistance with doxy-PEP?
Yes No

Gonorrhea & Doxycycline Resistance

Concern of drug resistance with long-term use

- Benefit: in the research the “doxycycline group had a significantly lower percentage of quarterly visits in which participants tested positive for a bacterial STIs.” (Luetkemeyer AF et al. 2023)
- Risks: “The global community is desperately trying to reduce antibiotic use in an attempt to slow the seemingly inexorable rises in antibiotic resistance, and doxycycline is an important antibiotic for several common infections, including in the respiratory tract, and not just for the treatment of sexually transmitted infections. Data from patients taking doxycycline for acne indicate that its use will lead to doxycycline resistance in other bacteria, including potential pathogens, and calls have been made to limit the use of doxycycline for acne. Theoretical concerns also exist about resistance to syphilis or chlamydia and the inevitable increased resistance to *Neisseria gonorrhoeae*.” (Fairley & Chow, 2018)

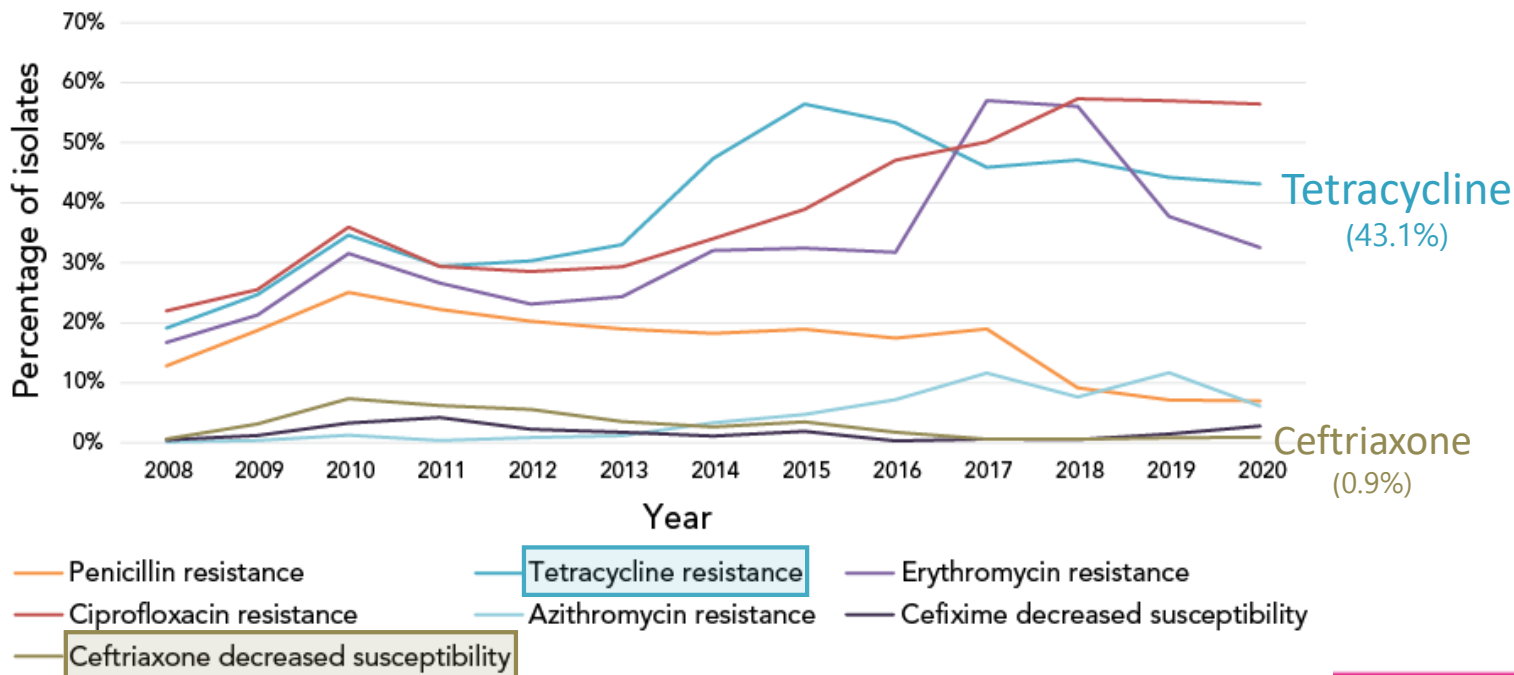
Luetkemeyer AF et al. (2023). Postexposure Doxycycline to Prevent Bacterial Sexually Transmitted Infections.
DOI: 10.1056/NEJMoa2211934

Fairley & Chow (2018). Doxycycline post-exposure prophylaxis: let the debate begin. *The Lancet.com/infection*.
Vol.18, p.234

“My goal as a physician is to make sure my patients are able to have whatever type of sex they want and however much sex they want as safely as possible,” said Boghuma Kabisen Titanji, an infectious diseases specialist in Atlanta. “And if DoxyPEP would allow them to do it, then I have no problem offering it.”

“We have used doxycycline for multiple other things,” Shira Heisler, medical director of the Detroit Public Health STD Clinic, said during a May conference of the National Coalition of STD Directors. “And I think specifically now being like, ‘We are not going to do it because of antimicrobial resistance’ when it’s specifically related to STIs is a good time to call out, ‘This is what stigma is. This is what bias is.’”

Gonorrhoea Resistance: Canada



Thorington et al (PHAC). Antimicrobial susceptibilities of *Neisseria gonorrhoeae* in Canada, 2020. Can Commun Dis Rep 2022;48(11/12):571–9. Available from: <https://www.canada.ca/en/public-health/services/reports-publications/canada-communicable-disease-report-ccdr/monthly-issue/2022-48/issue-11-12-november-december-2022/antimicrobial-susceptibilities-neisseria-gonorrhoeae-canada-2020.html>

Doxycycline Resistance:

Doxy PEP in ANRS IPERGAY study

9 positive gonorrhea cultures from 8 participants

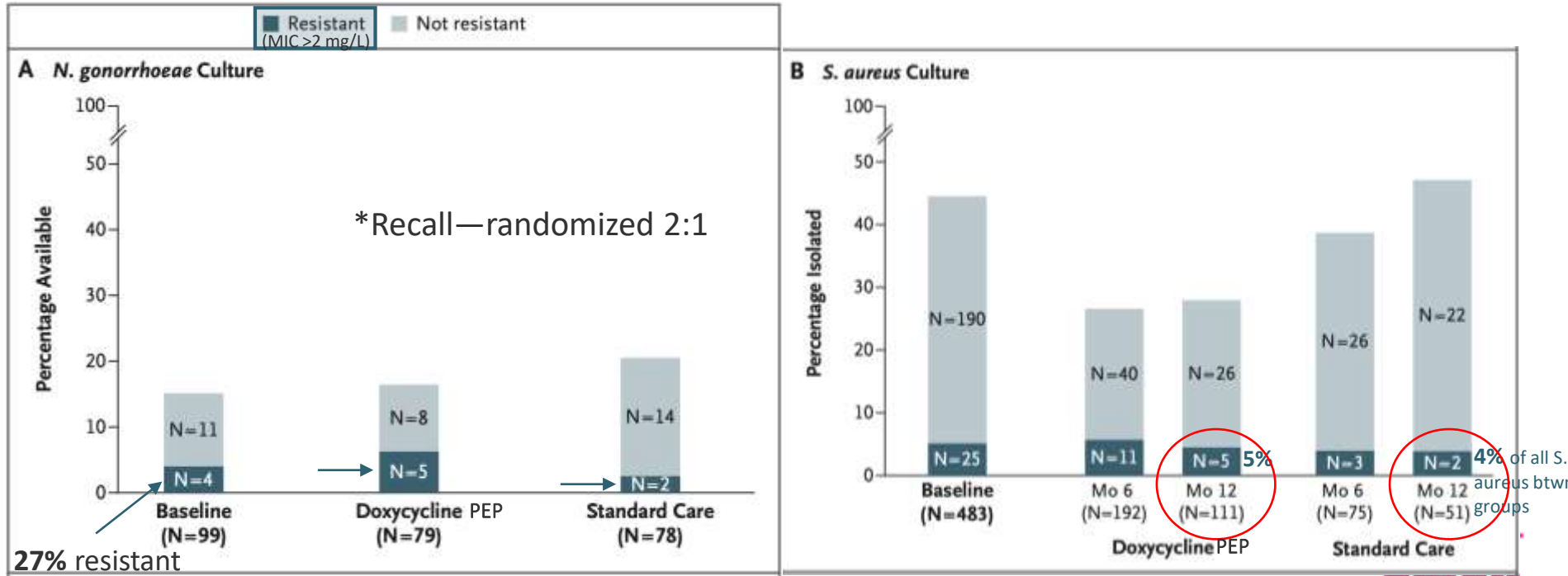
- 2 participants from doxy-PEP group, and
- 6 participants from no-PEP group

Authors note:

- (Full) tetracycline resistance (MIC > 1mg/L) detected for 4 isolates
 - **All from *no-PEP* group**
- Intermediate resistance (MIC > 0.5mg/L) for 3 isolates

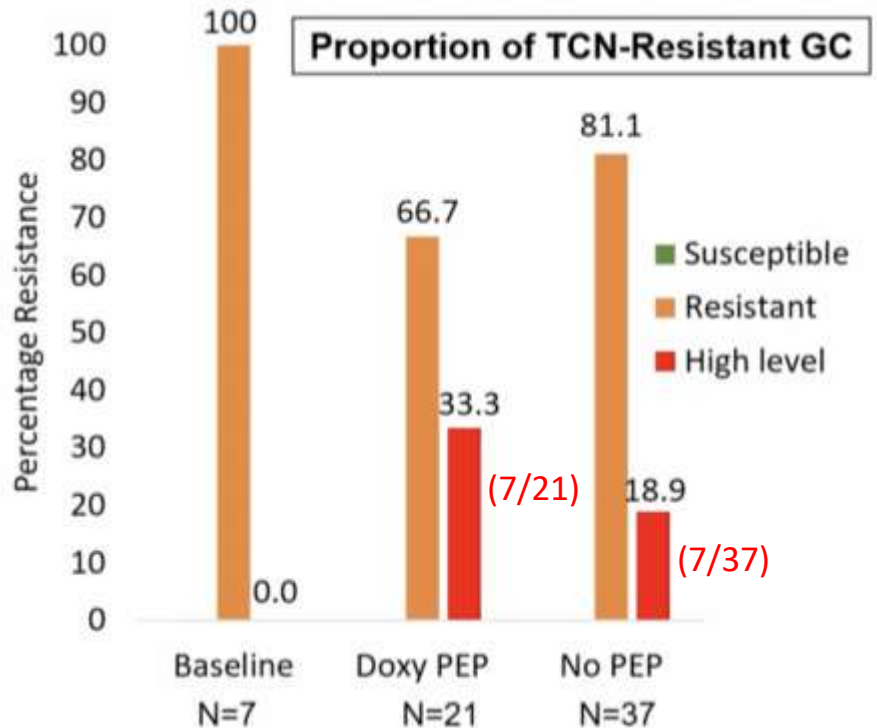
Doxycycline Resistance:

DoxyPEP Study to Prevent Bacterial STIs



Doxycycline Resistance: DOXYVAC Trial

- **GC:**
 - 65 cultures available for resistance testing (15% of PCR positive samples)
 - Tetracycline MICs determined by Etest
 - Resistance using EUCAST 2023 breakpoints
 - Resistance: MIC > 0.5 mg/L
 - High level resistance: MIC > 8 mg/L



Case Scenario

Case Scenario: What would you do?

A 31-year-old cisgender MSM presents to clinic requesting doxy-PEP, which he had read about online.

(What additional info would you want to know?)

- On HIV PrEP, gets regular testing (at least) q3mos
- STI Hx: positive for primary syphilis x1 and pharyngeal gonorrhea x1 over the past year
- Endorses condomless oral sex 100% of the time, and condomless anal sex (insertive + receptive) ~90% of the time
- Approximates 5-10 casual partners on the average month
- Does not anticipate any changes to his sexual practices

Poll 6: What would you do?

- 31 y.o., cis MSM
- On HIV PrEP, testing (at least) q3mos
- Syphilis x1 and gonorrhea x1 past yr
- Frequent condomless oral + anal sex

Options:

- a) Prescribe Doxy-PEP
- b) Gather more info from patient before deciding
- c) Do not prescribe Doxy-PEP

Summary

- 3 large studies on doxy-PEP have shown significant reductions of bacterial STIs among MSM
- Doxy-PEP now part of standard of care in California; some local (Ontario) HCPs also prescribing
- Doxy-PEP is well-tolerated with high self-reported adherence
- Evaluation of full impact on antibiotic resistance is underway

DOXYCYCLINE PEP FOR PREVENTION OF SEXUALLY TRANSMITTED INFECTIONS

WRITTEN BY DEVAN NAMBIAR, MSC.
REVIEWED BY JORDAN GOODRIDGE (BHSC, MD, CCFP)

JUNE 12, 2023



<https://gmsh.ca/wp-content/uploads/2023/06/GMSH-Pep-for-STI-Prevention-2023-1.pdf>

GMSH online

<https://www.gmsh.ca/>

<https://www.thesexyouwant.ca/>

<https://www.partyandplay.info/>

<https://www.getprimed.ca/>

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YouTube: [@GayMensSexualHealthAlliance](https://www.youtube.com/GayMensSexualHealthAlliance)

TikTok: [@GMSHAlliance](https://www.tiktok.com/GMSHAlliance)

Facebook: [@GMSHAlliance](https://www.facebook.com/GMSHAlliance)

Twitter: [@GMSHAlliance](https://www.twitter.com/GMSHAlliance)

DISCO study is enrolling participants


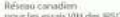
The DISCO study website includes information on the use of doxycycline as PrEP or PEP for anyone interested and study staff contact information for each participating site. The link for the website is:

<https://www.godisco.ca/>


3 sites: Toronto, Ottawa and Hamilton


CTN 329:
disco

The Doxycycline Intervention for Bacterial STI Chemoprophylaxis Study

 CHIV Canadian
HIV Trials Network  Réseau canadien
pour les essais VIH des RSC

The Doxycycline Intervention for bacterial STI Chemoprophylaxis (DISCO) study is the first methodologically rigorous randomized controlled trial looking at using the antibiotic doxycycline either pre-exposure or post-exposure to prevent bacterial STIs (syphilis, gonorrhoea, or chlamydia).





Discussions, Q & A



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STRENGTHENING THE RESPONSE TO STIS

Leading. Advocating. Educating. Connecting.

DOXY AS STI PEP COMMAND CENTER

Find out the 2022 timeline, next steps, and an implementation guide to begin offering Doxyline as STI PEP to patients in your community.

DOXY AS STI PEP COMMAND CENTER

[Doxy as STI PEP Command Center | NCSD \(ncsddc.org\)](https://www.ncsddc.org/resource/doxy-as-sti-pep-command-center/) <https://www.ncsddc.org/resource/doxy-as-sti-pep-command-center/>

Appendix

CDC: Doxycycline as STI PEP: Considerations for Individuals and Healthcare Providers of Gay or Bisexual Men or Transgender Women

- [Current efficacy data](#) only applies to gbMSM, and transgender women. Studies among heterosexual cis-gender women are ongoing.
- Doxycycline 200 mg administered within 24-72 hours of condomless sex was the regimen evaluated in this study. Other antibiotics should not be considered for PEP.
- In addition to informing patients about the potential STI prevention benefits of doxy as PEP, providers should also counsel patients about potential adverse side effects of doxycycline including phototoxicity, gastrointestinal symptoms, and more rarely esophageal ulceration.
- Providers should continue to screen, test, and treat for bacterial STIs in accordance with [CDC's STI Treatment Guidelines](#) and [CDC's PrEP for the Prevention of HIV guidelines](#), even among people who may be using doxycycline as PEP or PrEP.

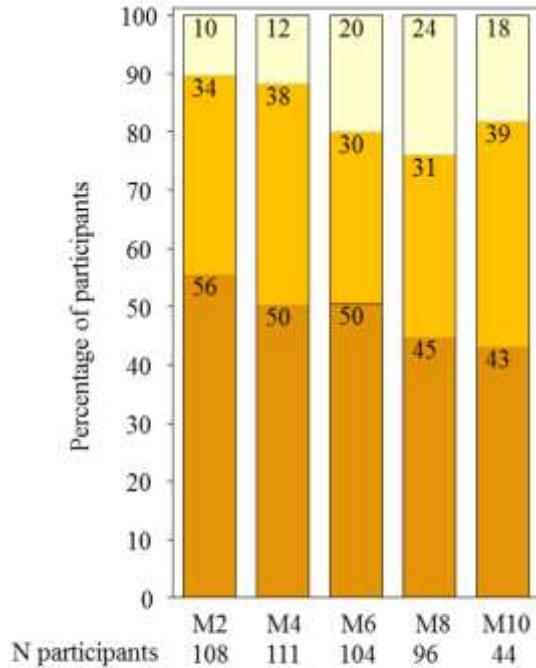
DoxyPEP in ANRS IPERGAY study

Gonorrhea (PCR+)	PEP		NO PEP		TOTAL		P value
	No. STI	No. symptomatic STI	No. STI	No. symptomatic STI	No. STI	No. symptomatic STI (%)	
Anus	11	1	19	5	30	6 (20)	
Throat	15	0	12	1	27	1 (4)	
Urine	1	1	7	5	8	6 (75)	
Total sites	27	2	38	11	65	13 (20)	
Total infections	27		30		57		
Rate of infection/100 PY	32.6		37.3				0.63
Chlamydia (PCR+)	No. STI	No. symptomatic STI	No. STI	No. symptomatic STI	No. STI	No. symptomatic STI (%)	P value
	No. STI	No. symptomatic STI	No. STI	No. symptomatic STI	No. STI	No. symptomatic STI (%)	
Anus	6	1	18	3	24	4 (17)	
Throat	2	0	1	1	3	1 (33)	
Urine	1	0	8	2	9	2 (22)	
Total sites	9	1	27	6	36	7 (19)	
Total infections	8		24		32		
Rate of infection/100 PY	9.7		29.9				0.008

Table S1. Sites of gonorrheal and chlamydial infections

Luetkemeyer AF et al. (2023). Postexposure Doxycycline to Prevent Bacterial Sexually Transmitted Infections. DOI: 10.1056/NEJMoa2211934
 Fairley & Chow (2018). The Lancet.com/infection. Vol.18, p.234

DoxyPEP in ANRS IPERGAY study



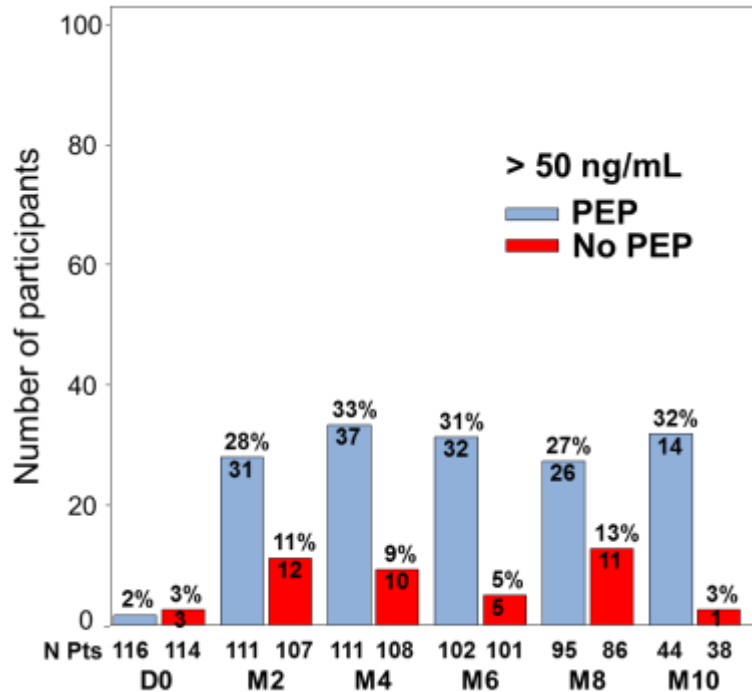
Adherence: Self-reported

Figure S1: Patterns of doxycycline use during sexual intercourse in the post-exposure prophylaxis arm at each two-monthly (M) visit. Three categories of pill use were defined at each visit: No doxycycline use, doxycycline use but not for all at risk sexual intercourses, doxycycline use for all condomless sexual intercourses. 9/476 visits (2%) had missing data

- Yes, following all intercourses at risk
- Yes, but not for all intercourses at risk
- No

Use Doxycycline to Prevent Bacterial Sexually Transmitted Infections.

DoxyPEP in ANRS IPERGAY study



Adherence: detectable plasma levels

Figure S2: Proportions of participants with detectable plasma levels of doxycycline in blood among the 116 enrolled subjects assigned to doxycycline post-exposure prophylaxis (PEP) group and the 116 subjects enrolled in the no PEP group. Limit of quantification is 50 ng/mL.

Luetkemeyer AF et al. (2023). Postexposure Doxycycline to Prevent Bacterial Sexually Transmitted Infections.

DOI: 10.1056/NEJMoa2211934

Fairley & Chow (2018). The Lancet.com/infection. Vol.18, p.234

DoxyPEP in ANRS IPERGAY study

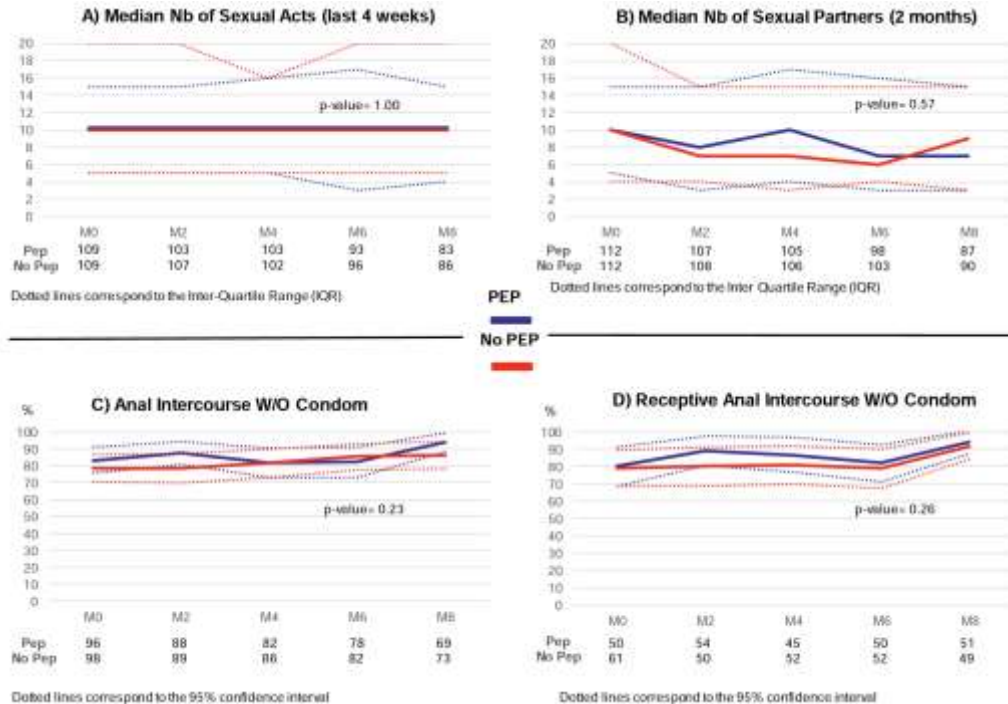


Figure S3: Median number of sexual acts in last 4 weeks during follow-up in the doxycycline post-exposure prophylaxis (PEP) and the no PEP groups (A).

Median number of sexual partners in last two months during follow-up in the PEP and no PEP groups (B).

Proportion of anal intercourse without a condom at last sexual intercourse during follow-up in the PEP and no PEP groups (C).

Proportion of receptive anal intercourse without a condom at last sexual intercourse during follow-up in the PEP and no PEP groups (D).

Luetkemeyer AF et al. (2023). Postexposure Doxycycline to Prevent Bacterial Sexually Transmitted Infections.

DOI: 10.1056/NEJMoa2211934

Fairley & Chow (2018). The Lancet.com/infection. Vol.18, p.234

Doxy PEP Study to Prevent Bacterial STIs

	PrEP	Living with HIV	Total
Participants* (ITT population)	327	174	501
Age	36 (31 - 42)	43 (36 - 54)	38 (32 - 47)
Race			
White	210 (67%)	111 (66%)	321 (67%)
Black	14 (5%)	22 (13%)	36 (8%)
Asian/Pacific Islander	45 (14%)	8 (5%)	53 (11%)
Multiple races/other	44 (14%)	28 (17%)	72 (15%)
Ethnicity: Hispanic/Latino	96 (29%)	55 (32%)	151 (30%)
Gender identity			
Man	319 (98%)	163 (94%)	482 (96%)
Trans woman/gender diverse	8 (2%)	11 (6%)	19 (4%)
Gender of sexual partners: Male only	281 (86%)	153 (88%)	434 (87%)
STI in past 12 months**			
Gonorrhea	233 (71%)	110 (63%)	343 (69%)
Chlamydia	207 (63%)	85 (49%)	292 (58%)
Syphilis†	48 (15%)	52 (30%)	100 (20%)
Sexual partners in past 3 months	9 (4 - 17)	8.5 (3 - 20)	9 (4 - 17)
Substance use in past 3 months	178 (55%)	115 (68%)	293 (59%)
Stimulants (methamphetamine, cocaine, crack)	73 (23%)	73 (43%)	146 (30%)
Ecstasy, GHB, ketamine	97 (30%)	60 (35%)	157 (32%)

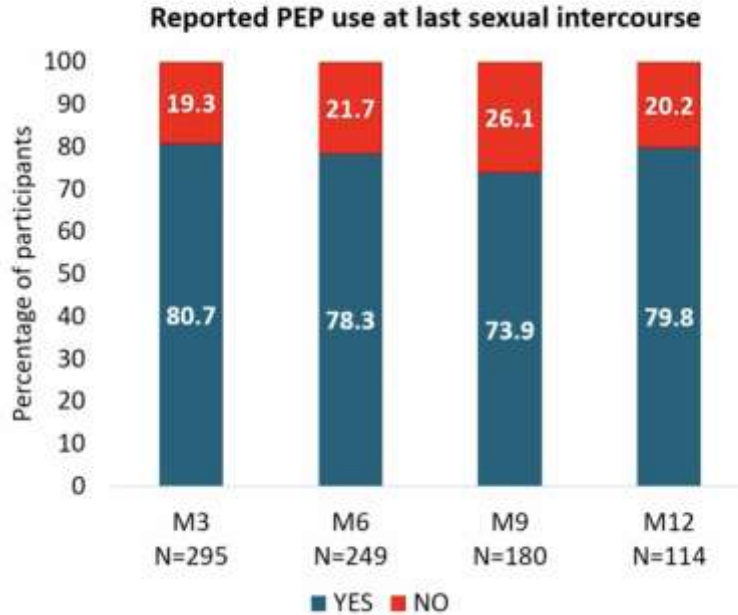
Luetkemeyer A
doi: 10.1056/M

DoxyPEP Study to Prevent Bacterial STIs

- DoxyPEP study permitted up to daily administration of doxycycline, with a **median of 4 doses reported per month**; however, **25% of the participants took 10 doses or more** on the basis of the interquartile range, with 86% participant-reported adherence with condomless sex
- Vs the **IPERGAY study** limited participants to a **weekly maximum of 3 doses of 200-mg doxycycline**; an average of 3.4 doses were taken per month

DOXYVAC Trial

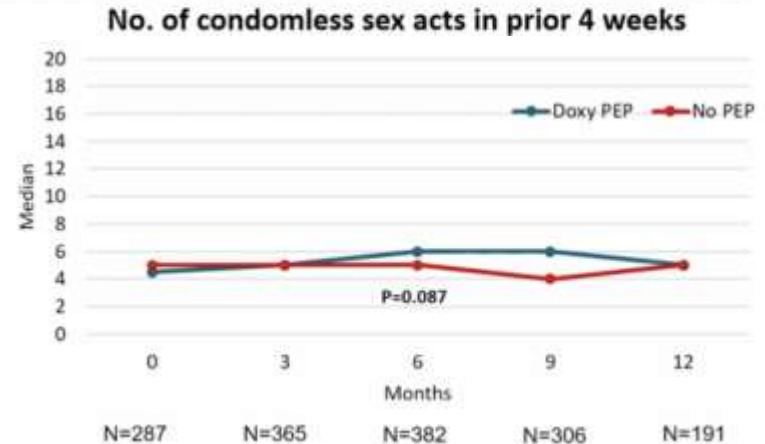
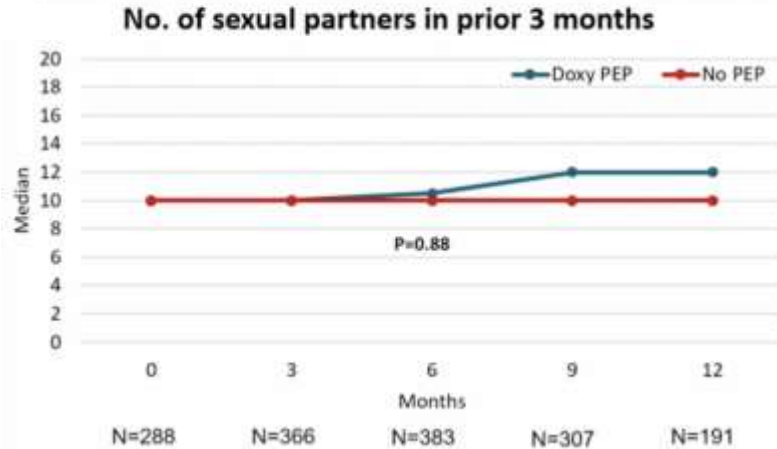
Self-Reported Adherence to Doxy PEP



- Median (IQR) time to PEP intake: 27h (5-33) after sex
- Median no. of pills/month (IQR): 7 pills (4-11)
- 3 (0.9%) discontinued PEP: GI AEs (n=2) and fear of AEs (n= 1)

DOXYVAC Trial

Changes in Sexual Behavior



DOXYVAC Trial

Microbiome Analysis

