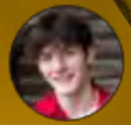
Effectiveness of doxycycline as post-exposure prophylaxis (Doxy-PEP) for bacterial sexually transmitted infections (STIs) among men who have sex with men (MSM) in Central Florida



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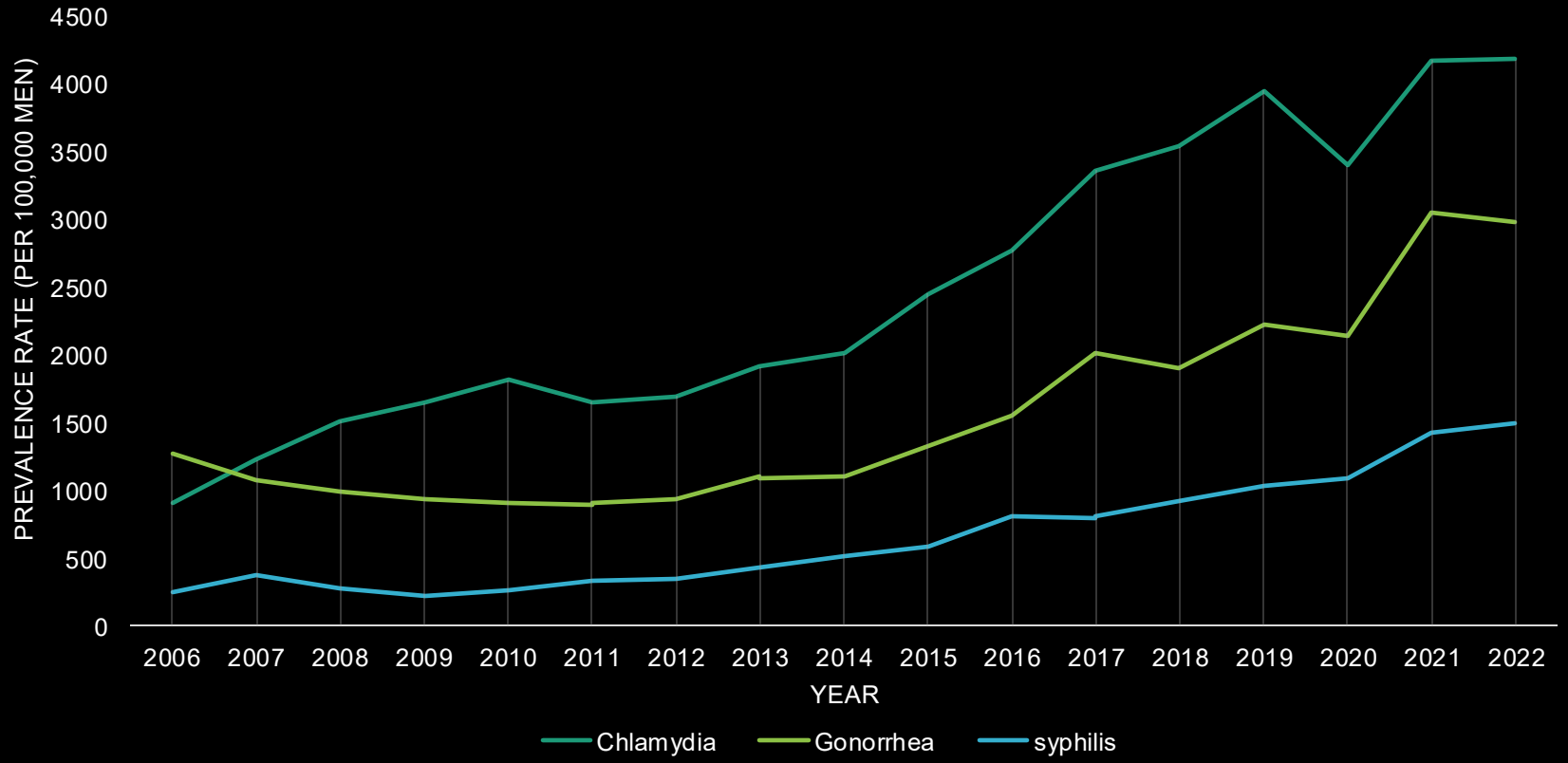
Disclosures

- Conflicts of Interest
  - None relevant to this presentation
- Ethical Review
  - UCF's IRB STUDY00005934
- Disclaimer
  - Doxycycline use is not approved by the FDA as DoxyPEP

Bacterial STI prevalence rates (per 100,000 men) in Orange County, Florida. 2006-2022

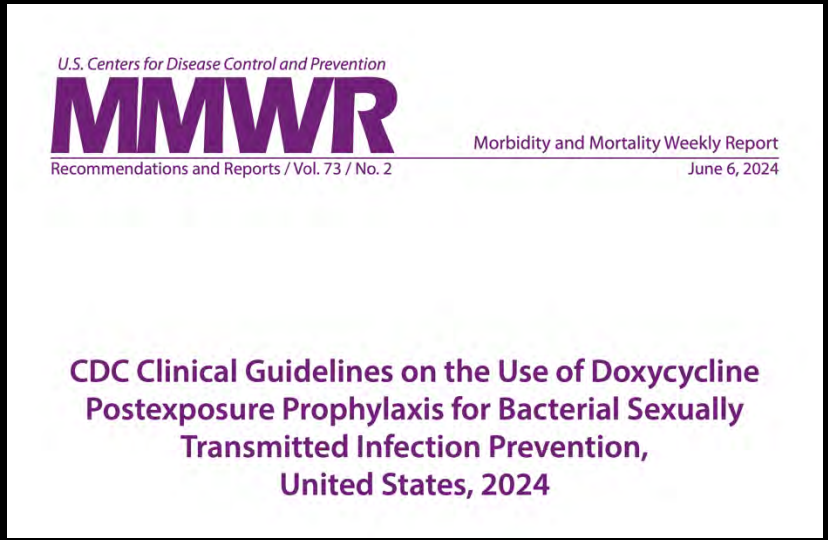


Background

- Bacterial STI incidence rates among MSM have been rising, particularly in the US
- The CDC (2019) reported a 375.5% increase in gonorrhea and a 4-fold increase in chlamydia prevalence among MSM from 2010 to 2018
- Uptake of PrEP for HIV may contribute to increased condomless sexual acts among MSM
- Recent randomized, controlled clinical trials (Luetkemeyer et al., 2023; Molina et al., 2023) have shown promising **effectiveness** of Doxy-PEP as intervention

What is DoxyPEP?

- Doxycycline (any formulation) 200 mg once within 72 hours of oral, vaginal, or anal sex
- Not to exceed 200 mg/24 hr
- Reassess ongoing need every 3-6 mo



Bachmann LH, Barbee LA, Chan P, et al. CDC Clinical Guidelines on the Use of Doxycycline Postexposure Prophylaxis for Bacterial Sexually Transmitted Infection Prevention, United States, 2024. *MMWR Recomm Rep*. 2024;73(2):1-8. Published 2024 Jun 6. doi:10.15585/mmwr.rr7302a1

Who should receive DoxyPEP?

BOX 1. CDC recommendations for use of doxycycline as postexposure prophylaxis for bacterial sexually transmitted infections prevention

Recommendation*	Strength of recommendation and quality of evidence†
• Providers should counsel all gay, bisexual, and other men who have sex with men (MSM) and transgender women (TGW) with a history of at least one bacterial sexually transmitted infection (STI) (specifically, syphilis, chlamydia or gonorrhea) during the past 12 months about the benefits and harms of using doxycycline (any formulation) 200 mg once within 72 hours (not to exceed 200 mg per 24 hours) of oral, vaginal, or anal sex and should offer doxycycline postexposure prophylaxis (doxy PEP) through shared decision-making. Ongoing need for doxy PEP should be assessed every 3–6 months.	AI High-quality evidence supports this strong recommendation to counsel MSM and TGW and offer doxy PEP.
• No recommendation can be given at this time on the use of doxy PEP for cisgender women, cisgender heterosexual men, transgender men, and other queer and nonbinary persons.	Evidence is insufficient to assess the balance of benefits and harms of the use of doxy PEP

* Although not directly assessed in the trials included in these guidelines, doxy PEP could be discussed with MSM and TGW who have not had a bacterial STI diagnosed during the previous year but will be participating in sexual activities that are known to increase likelihood of exposure to STIs.
† See Table.

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Research Question

- Is the **effectiveness** of DoxyPEP among MSM in Central Florida comparable to the **efficacy** reported by HIV status in randomized controlled trials?

Materials and Methods

IRB STUDY00005934

Materials and Methods

- Secondary data analysis of a de-identified dataset provided by Pineapple Healthcare, a primary care practice in Orlando, Florida, specializing in diagnosing and managing IDs
- **Inclusion criteria:** Cisgender men, 18 years or older, received Doxy-PEP between July 1st and July 30th, 2023, baseline and follow-up test for chlamydia, gonorrhea, and/or syphilis, and have had sex with a man in the past 12 months
- **Study Variables:** age, race, ethnicity, sexual orientation, height, weight, BMI, other medications, dates of doxy-PEP, baseline and follow-up STI testing

Analyses

- SPSS v. 28 (The IBM Corp., Armonk, NY):
  - Descriptive analyses (mean, median, standard deviation, etc.)
  - Calculation of incidence rates per 100 for bacterial STIs (gonorrhea, chlamydia, syphilis)
- MedCalc v. 22.021
  - Significance of incidence rates identified in this study vs benchmark values, with stratification by HIV status.

Results

Results

- The per-protocol analytic sample included 73 MSM meeting the inclusion criteria
- Besides significant differences in participants' age by HIV status, no other differences were noted in terms of demographic characteristics
- The highest incidence rate was observed in the HIV-positive cohort for syphilis as well as a higher incidence overall for any STI
- For every STI (except gonorrhea), the HIV negative cohort showed lower incidence rates than the HIV positive cohort
- There were no cases of chlamydia in the HIV negative cohort and there were no cases of gonorrhea in the HIV positive cohort
- HIV negative and HIV positive groups showed significant differences in syphilis incidence rates

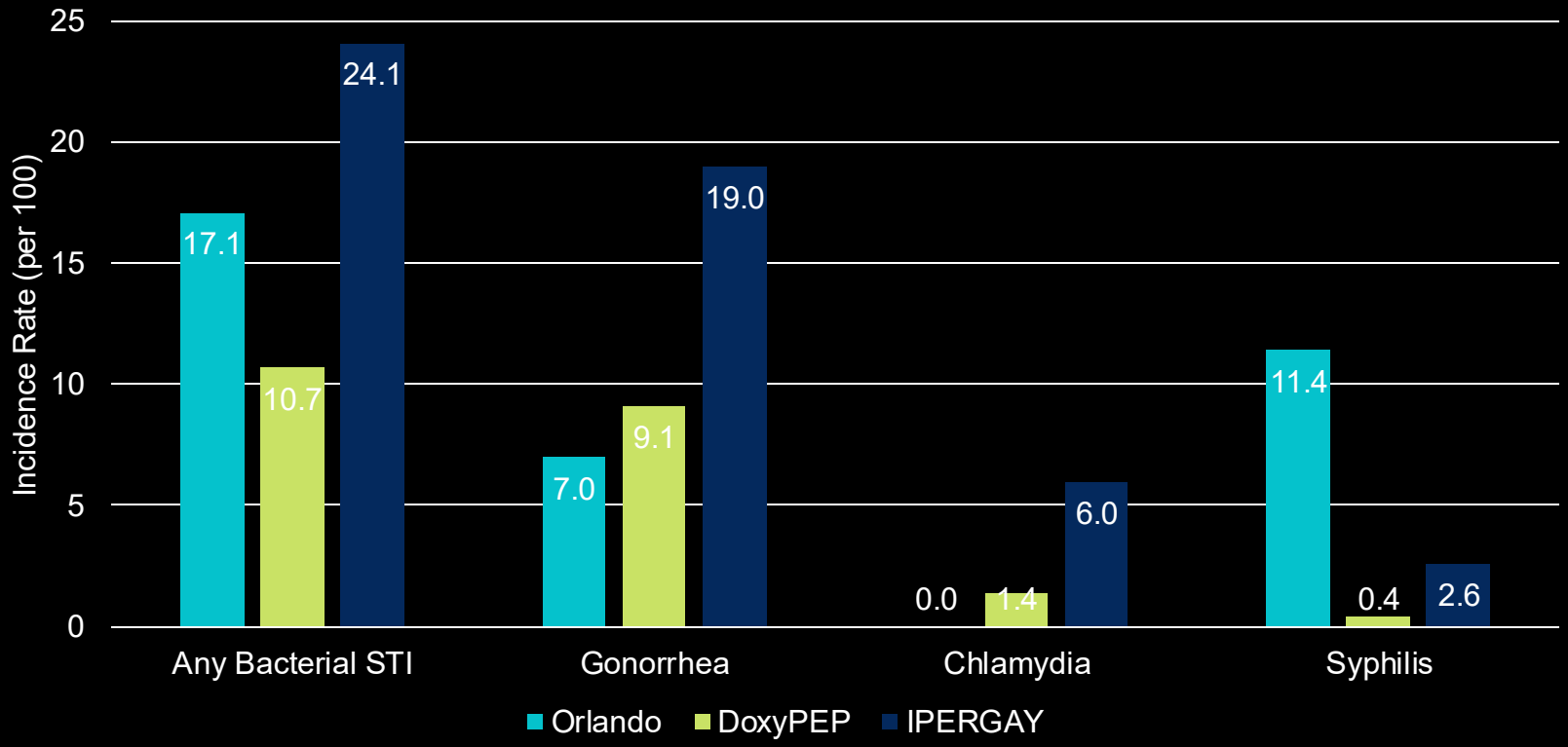
Demographic characteristics by HIV status

	HIV Negative (*n*=52)	HIV Positive (*n*=20)	Overall (*n*=73)	*P* value[a]
Age, years, mean (SD)	34.1 (8.1)	39.6 (8.1)	35.6 (8.4)	.01
Race, *n* (%)				.62
White	46 (88.5%)	16 (80.0%)	62 (84.9%)	
Asian	2 (3.8%)	—	2 (2.7%)	
Black	3 (5.8%)	2 (10.0%)	5 (6.8%)	
Hispanic	1 (1.9%)	1 (5.0%)	2 (2.7%)	
Ethnicity, *n* (%)				.20
Non-Hispanic	27 (51.9%)	7 (35.0%)	34 (46.6%)	
Hispanic	23 (44.2%)	12 (60.0%)	35 (47.9%)	
Sexual orientation, *n* (%)				.40
Heterosexual	2 (3.8%)	—	2 (2.7%)	
Bisexual	2 (3.8%)	2 (10.0%)	4 (5.5%)	
Gay	47 (90.4%)	17 (85.0%)	64 (87.7%)	
BMI, kg/m^2, mean (SD)	29.7 (7.9)	27.4 (3.9)	29.0 (7.1)	.21

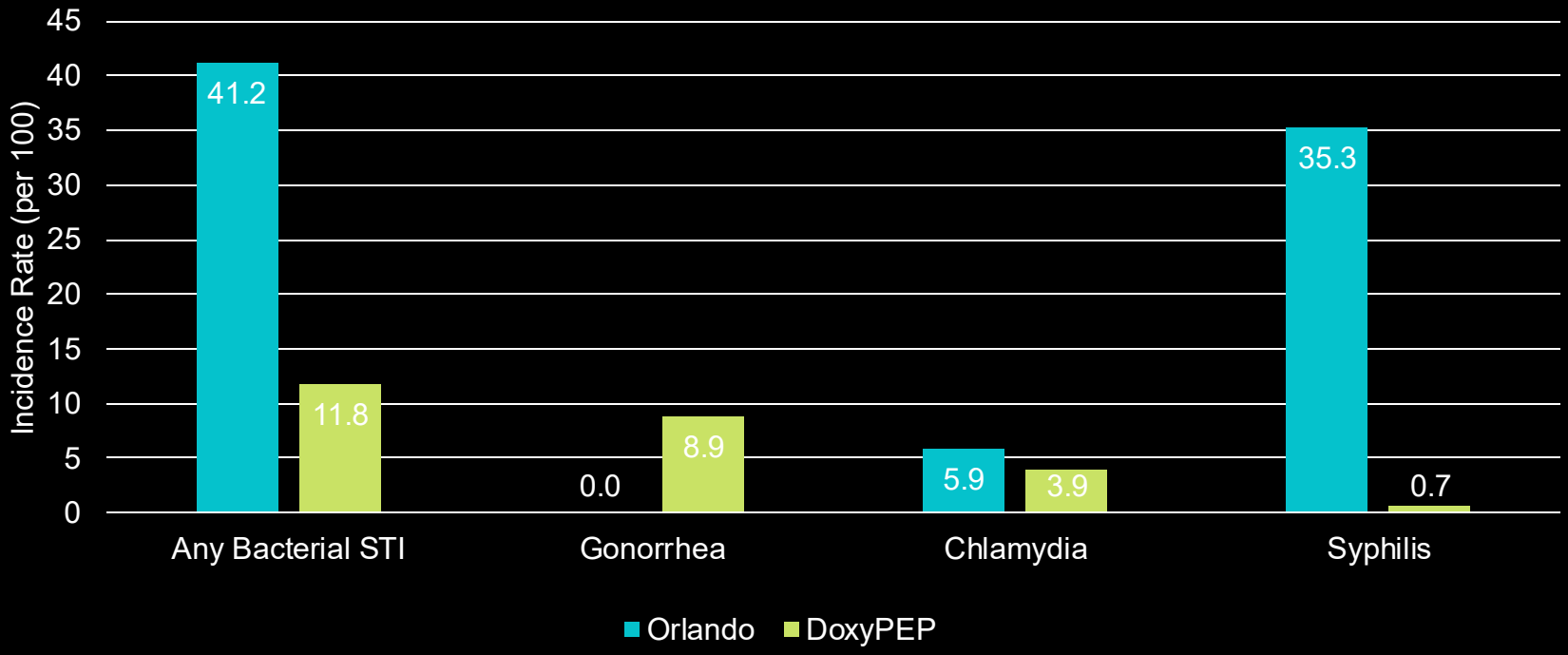
Incidence rates (per 100 men) of bacterial STIs after Doxy-PEP use by HIV status, as reported in 3 studies

	Orlando Study (Greer et al., 2024)			DoxyPEP Trial (Luetkemeyer et al., 2023)				IPERGAY Trial (Molina et al., 2023)	
	HIV− (*n*=52)	**HIV+ (*n*=20)**	***P* value[a]**	**HIV− (*n*=570)**	**P value[b]**	**HIV+ (*n*=305)**	***P* value[c]**	**HIV− (*n*=570)**	***P* value[b]**
Any Bacterial STI	7/41 (17.1%)	7/17 (41.2%)	0.053	61/570 (10.7%)	0.21	36/305 (11.8%)	<0.001	28/116 (24.1%)	0.31
Gonorrhea	3/43 (7.0%)	0/17 (—)	0.27	52/570 (9.1%)	0.64	27/305 (8.9%)	0.20	22/116 (19.0%)	0.04
Chlamydia	0/42 (—)	1/17 (5.9%)	0.12	8/570 (1.4%)	0.44	12/305 (3.9%)	0.68	7/116 (6.0%)	0.10
Syphilis	5/44 (11.4%)	6/17 (35.3%)	0.03	2/570 (0.4%)	<0.001	2/305 (0.7%)	<0.001	3/116 (2.6%)	0.02

Incidence rates of bacterial STIs (per 100) after DoxyPEP use in three cohorts of MSM who are HIV negative



Incidence rates of bacterial STIs (per 100) after DoxyPEP use in two cohorts of MSM who are HIV positive



Limitations

- Significantly older cohort of men living with HIV may skew results
- Sample size and clinical setting are locally limited, questions about generalizability
- Differences in medication use (PrEP/ART for HIV, other medications not accounted for) may confound results
- DoxyPEP is not FDA approved for this indication

Conclusions

- While Doxy-PEP seems to be as efficacious in real life practice as it was effective in clinical trials, we observed nuanced responses to syphilis that warrant further studies
- All in all, Doxy-PEP seems to be an efficacious strategy to prevent bacterial STIs among MSM in Central Florida

Thank you!

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