1151

Doxy-PEP Effectiveness in Men Who Have Sex with Men (MSM) and Transgender Women (TGW) on HIV PrEP

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BACKGROUND

- Doxycycline 200 mg 24-72 hours after condomless oral or anal sex (doxy-PEP) reduced incidence of chlamydia (CT), gonorrhea (GC), and early syphilis (ES) in MSM and TGW with CT, GC, or ES in the previous year, in randomized trials [1-2].
- San Francisco City Clinic (SFCC) started offering doxy-PEP to MSM and trans persons with 2+ sex partners *or* CT, GC, or ES in the previous year, per citywide guidelines[3] on 11/3/2022.
- **Question**: what is the change in STI positivity among doxy-PEP users compared with non-users in a non-trial setting?

METHODS

- **Comparison groups**: MSM and TGW on HIV PrEP at SFCC with visits in both 11/3/2021 – 11/2/2022 and 11/3/2022-11/2/2023 divided into
  - **Doxy-PEP users**: positivity pre/post doxy-PEP prescription or reported use
  - **Non-users**: never started doxy-PEP, positivity pre/post 11/3/22
- **Positivity**:
  - GC and CT: proportion of visits with a GC or CT test with at least one positive result.
  - ES: proportion of visits with a syphilis test that identified a new ES case.
- **Outcome**: change in CT, ES, and GC positivity for doxy-PEP users vs. non-users using a GEE model with robust variance to account for repeated measures.

In MSM and TGW on HIV-PrEP who started doxy-PEP:
Chlamydia decreased 90% (95% CI 79% - 95%) and
Early syphilis decreased 56% (95% CI 8% - 79%)

RESULTS

- Of 506 patients on PrEP with visits in both time periods, 367 (73%) started doxy-PEP (users) and 139 did not (non-users).
- GC and CT positivity was higher in the pre-period among those who subsequently initiated doxy-PEP, compared with those who did not initiate doxy-PEP
- CT positivity decreased 90% (RR 0.10, 95% CI 0.05 – 0.21) among doxy-PEP users vs. 27% (RR 0.73, 95% CI 0.44–1.21) among non-users (Table). The reduction among doxy-PEP users was significantly greater than among non-users (Figure 1).
- Early syphilis positivity decreased 56% (RR 0.44, 95% CI 0.21 – 0.92) among doxy-PEP users vs. 32% (RR 0.68, 95% CI 0.20–2.30) among non-users (Table). The reduction among doxy-PEP users was *not* significantly greater than among non-users (Figure 2).
- There were nonsignificant decreases in GC positivity in users and nonusers (Table, Figure 3)

Chlamydia, Gonorrhea, and Early Syphilis Positivity at SF City Clinic:
Pre (11/3/21-11/2/22) and Post (11/3/22-10/30/23) Doxy-PEP Guidelines or Initiation

STI	Doxy-PEP Group	Exposure	# patients	Positivity: + tests/visits (%)	% decrease in positivity	Relative risk (95% CI)
Chlamydia	Ever doxy-PEP	Pre doxy-PEP initiation	366	164/1520 (10.8)	**90%**	**0.10 (0.05–0.21)**
		Post doxy-PEP initiation	293	8/708 (1.1)		
	Never doxy-PEP	Pre guidelines	135	26/320 (8.1)	27%	0.73 (0.44–1.21)
		Post guidelines	133	16/271 (5.9)		
Gonorrhea	Ever doxy-PEP	Pre doxy-PEP initiation	366	170/1518 (11.2)	23%	0.77 (0.58–1.02)
		Post doxy-PEP initiation	293	61/710 (8.6)		
	Never doxy-PEP	Pre guidelines	135	28/321 (8.7)	32%	0.68 (0.37–1.23)
		Post guidelines	133	16/271 (5.9)		
Early Syphilis	Ever doxy-PEP	Pre doxy-PEP initiation	366	40/1427 (2.8)	**56%**	**0.44 (0.21–0.92)**
		Post doxy-PEP initiation	289	8/648 (1.2)		
	Never doxy-PEP	Pre guidelines	135	7/298 (2.4)	32%	0.68 (0.20–2.30)
		Post guidelines	134	4/252 (1.6)		

Figure 1: Chlamydia Positivity

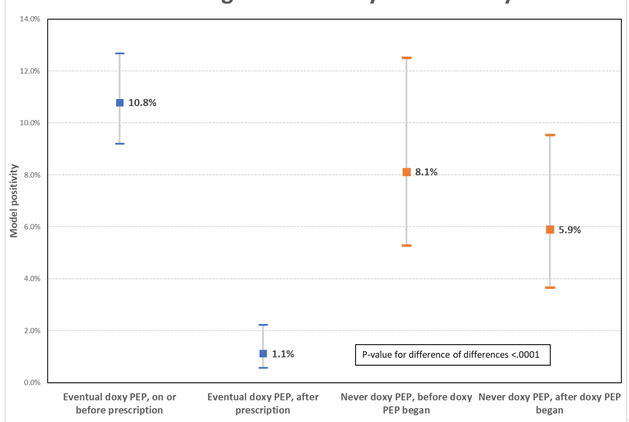


Figure 2: Early Syphilis Positivity

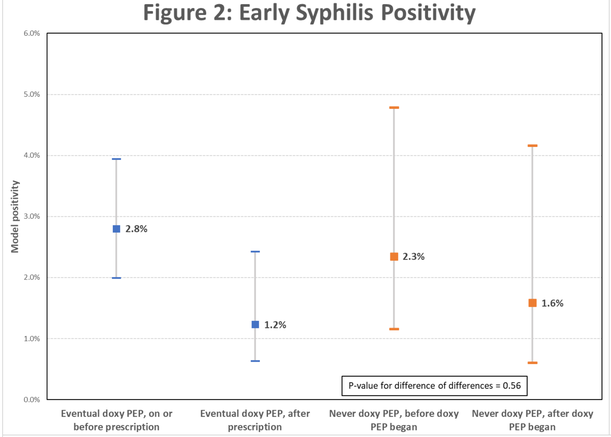
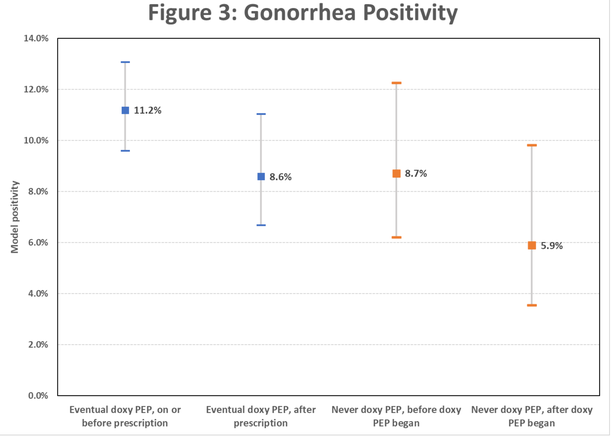


Figure 3: Gonorrhea Positivity



CONCLUSIONS/FUTURE DIRECTIONS

- Uptake of doxy-PEP among MSM and TGW receiving HIV PrEP at a sexual health clinic was high
- Those who started doxy-PEP had significantly reduced chlamydia and early syphilis positivity, unlike MSM and TGW on HIV PrEP who did not start doxy-PEP during the same period.
- Evidence was insufficient to prove that the decrease in early syphilis among doxy-PEP users differed significantly from the numerical decrease among non-users. This may be related to the relatively small number of syphilis cases.
- Doxy-PEP use had no effect on gonorrhea positivity. This may be related to tetracycline resistance in circulating strains of GC and/or to differences in adherence compared with the recently released doxy-PEP randomized trials.
- The reasons for the decline in CT, GC and ES in non-users, while not statistically significant, was unexpected and warrants further investigation.
- Longer-term evaluation of doxy-PEP in clinic-based cohorts is needed to assess these trends, monitor for adverse effects, and to evaluate how additional factors, including adherence, sexual behaviors and antimicrobial resistance impact doxy-PEP effectiveness

ADDITIONAL KEY INFORMATION

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1. Luetkemeyer et al. N Engl J Med 2023; 388: 1296-1306
2. Molina et al. (Feb 19-22) CROI 2023 Seattle, WA, USA, Abstract 119
3.San Francisco Department of Public Health (2022, Oct 21) Health Update.