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Preventing HIV and STIs: HIV PrEP and DoxyPEP Primer

Pensacola / South Alabama Update
April 24, 2024

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SOUTHEAST
STD/HIV PREVENTION
TRAINING CENTER
CONNECTING PROVIDERS PRACTICE & PATIENTS

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Disclosures

**Merck, Sharpe, Dohme, Inc. – Research funds to
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ViiV – Ad hoc Advisor

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Objectives

1. Review EHE Pillars
2. Apply HIV Pre-Exposure Prophylaxis (PrEP) Guidelines
3. Discuss Doxycycline Post-Exposure Prophylaxis (DoxyPEP)

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- **National Coordinating Resource Center** — serves as the central web-based repository for AETC Program training and capacity building resources; its website includes a free virtual library with training and technical assistance materials, a program directory, and a calendar of trainings and other events. Learn more: <https://aidsetc.org/>
- **National Clinician Consultation Center** — provides free, peer-to-peer, expert advice for health professionals on HIV prevention, care, and treatment and related topics. Learn more: <https://nccc/ucsf.edu>
- **National HIV Curriculum** — provides ongoing, up-to-date HIV training and information for health professionals through a free, web-based curriculum; also provides free CME credits, CNE contact hours, CE contact hours, and maintenance of certification credits. Learn more: www.hiv.uw.edu


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Ending the HIV Epidemic Strategies



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.





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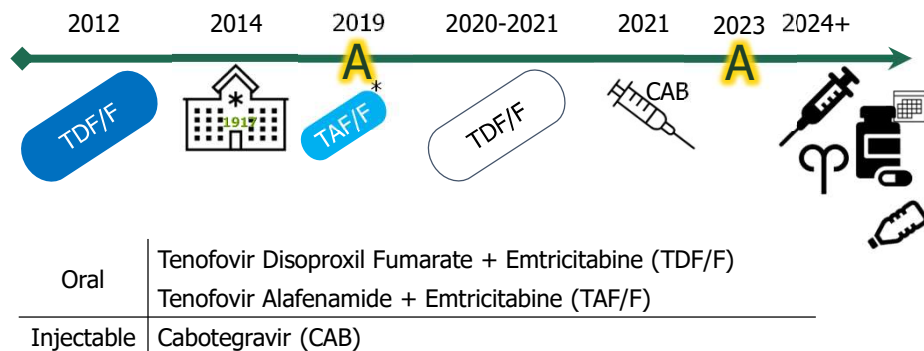
DHHS, accessed 2021
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What is Pre-Exposure Prophylaxis?

HIV Pre-Exposure Prophylaxis (PrEP)

- Chemoprophylaxis using antiretrovirals (ARV) taken before exposure to HIV



*not approved for vaginal exposures

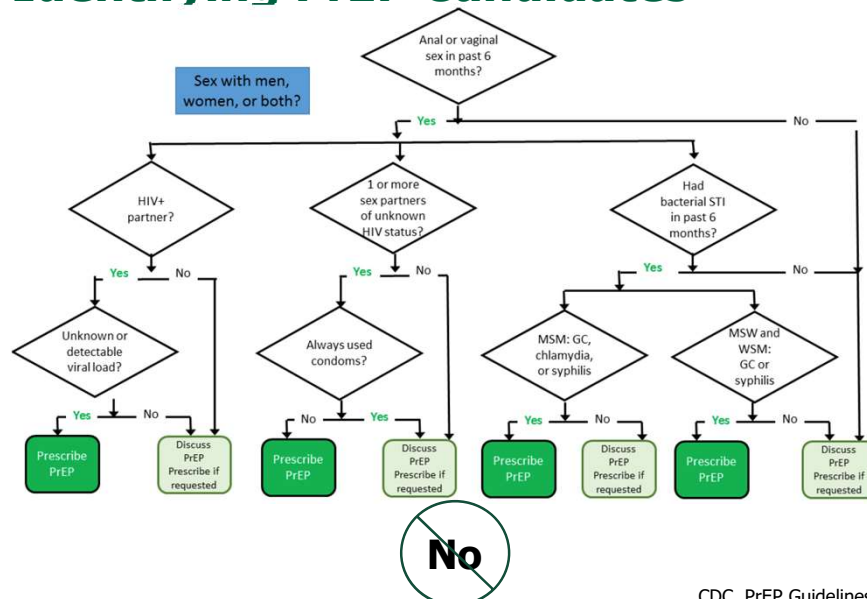
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Identifying PrEP Candidates



CDC, PrEP Guidelines 2021

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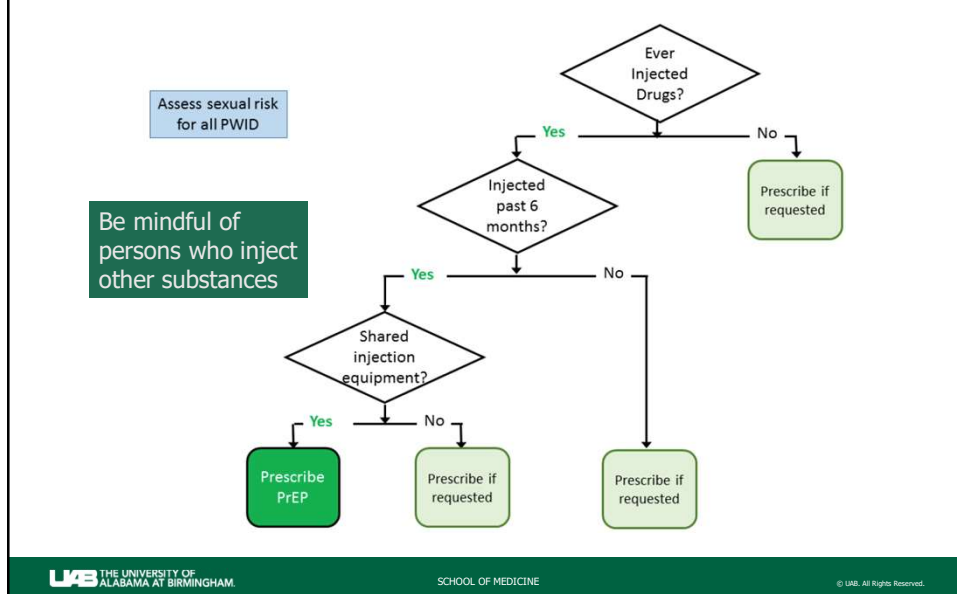
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Identifying PrEP Candidates

Figure 3 Assessing Indications for PrEP in Persons Who Inject Drugs



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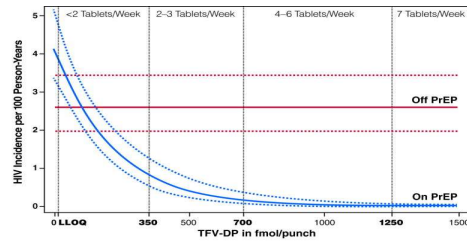
PrEP RCT Efficacy – Tenofovir

Trial	Population	Intervention	Outcome	Interpretation
iPrex	MSM & TGW	TDF/FTC vs Plac.	44% reduction, 92% if adherent	TDF/FTC effective
Partners PrEP	Serodifferent Heterosexual	TDF/FTC vs TDF vs Placebo	75% reduction among all	TDF/FTC effective
VOICE	Cis-Women	5 arms (oral & vag TDF v placebo)	Not effective, but poor adherence	Adherence matters most
Bangkok Tenofovir Study	PWID	TDF vs Placebo	49% reduction, 74% if adherent	TFV effective in PWID also
DISCOVER	MSM & TGW	TDF/F v TAF/F	0.34/100PY vs 0.16/100PY	TAF/F Noninferior
ANRS Ipergay	MSM & TGW	On-Demand TDF/F v Placebo	86% Risk Reduction	On-Demand effective also

Grant et al, NEJM 2010; Baeten et al, NEJM 2012; Marrazzo et al, NEJM 2015; Choopanya et al. Lancet 2013; Mayer et al. Lancet 2020; Molina et al, NEJM 2015

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Effectiveness Depends Adherence - TDF/FTC



MSM = 4x/week

Women = 6-7x/week

TFV-DP in DBS (fmol/punch)	BLQ	LLOQ to <350	350 to <700	700 to <1350	≥1350
Estimated Dosing (Tablets/Week)	None	2-3	4-6	7	7
Follow-up (% of Weeks)	25%	26%	12%	21%	13%
HIV Infections	18	9	1	0	0
Person Years	384	399	179	316	181
HIV Incidence Rate (95% CI)	4.70 (2.89-7.70)	2.26 (1.18-4.79)	0.56 (0.2-2.50)	0 (0-0.61)	0 (0-1.00)
HIV Prior Infection Reference (95% CI)	1.55 (0.88-2.56)	0.69 (0.32-1.32)	0.19 (0.01-0.38)	0 (0-0.25)	0 (0-0.50)
HIV Concurrent OR-PrEP Reference (95% CI)	1.25 (0.60-2.64)	0.56 (0.23-1.31)	0.16 (0.01-0.79)	0 (0-0.21)	0 (0-0.43)

- 7 days until protective in rectal tissues
- Rectal TFV-dp levels at least 10x higher than cervicovaginal tissues
- 21 days until protective in cervicovaginal tissues or blood

Hanscom et al. J AIDS 2016

Seifert et al. CID 2015.

Patterson et al. Sci Transl Med 2011

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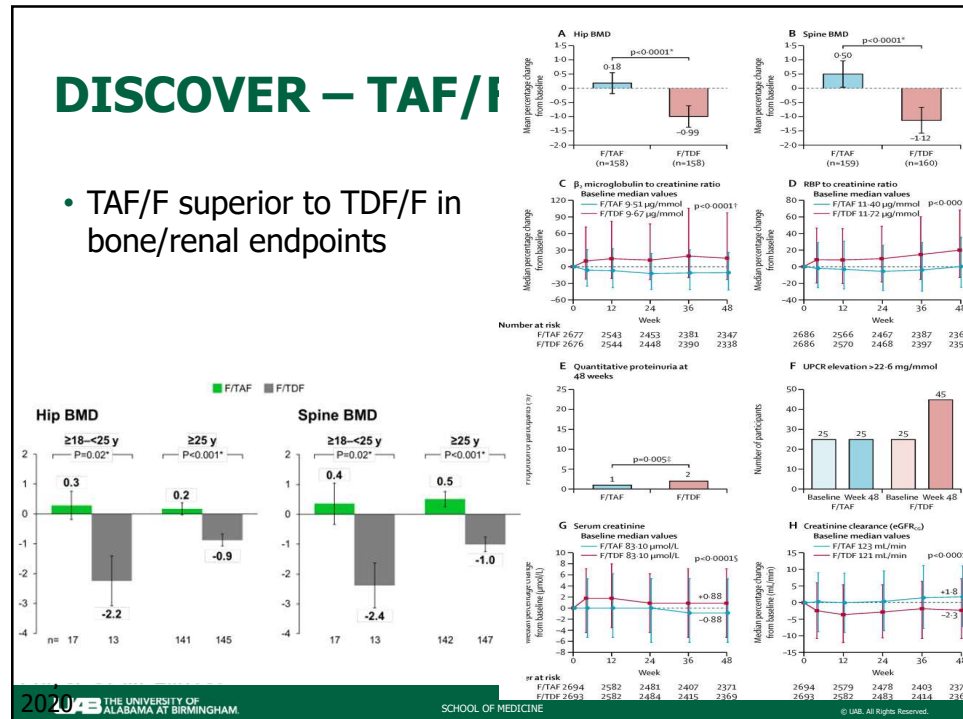
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DISCOVER – TAF/F

- TAF/F superior to TDF/F in bone/renal endpoints



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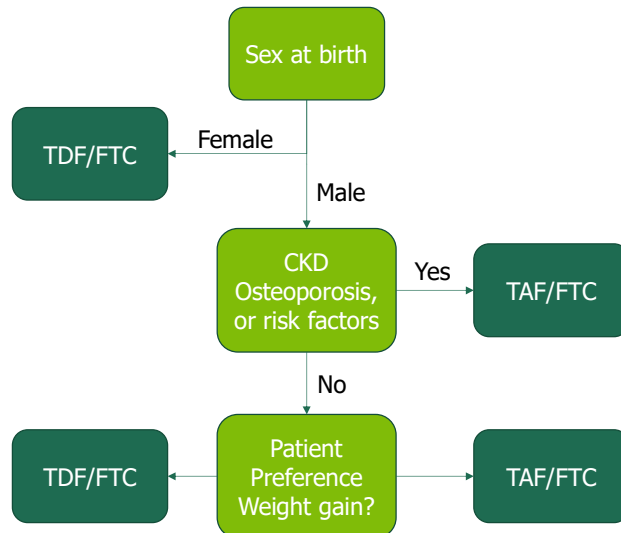
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Choosing PrEP: TDF/FTC or TAF/FTC?

Multiple factors:
patient preference,
sex at birth, co-
morbidities

- If the patient was assigned female sex at birth, then they can only use TDF/FTC. TAF/FTC is not approved for these persons.

- Co-morbid conditions such as CKD and osteoporosis should warrant using TAF/FTC



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Tenofovir Adverse Effects

	TAF/FTC (n=2694)	TDF/FTC (n=2693)
Any SE	545 (20%)	630 (23%)
Diarrhea	135 (5%)	160 (6%)
Nausea	114 (4%)	123 (5%)
Headache	59 (2%)	57 (2%)
Fatigue	43 (2%)	72 (3%)
Abdominal Pain	26 (1%)	35 (1%)
Flatulence	22 (<1%)	32 (1%)
Abdominal discomfort	18 (<1%)	30 (1%)
Weight Change	+1.1kg	-0.1kg
Fractures	53 (2%)	53 (2%)
Non-traumatic*	1 (<0.1%)	2 (<0.1%)

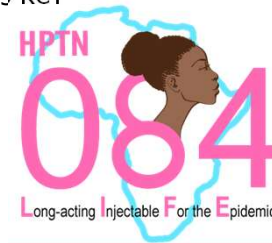
GI Effects rapidly declined over 2-4 weeks after starting PrEP

Mayer et al, Lancet 2020

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Long-Acting Cabotegravir

- FDA approved Cabotegravir for PrEP in December 2021
 - Approved for all persons regardless of sex assigned at birth
 - Adults and Adolescents >35kg
 - HPTN 083
 - MSM and TGW, global, multi-site Phase 3 RCT
 - HPTN 084
 - Cisgender Women, Sub-Saharan Africa, Phase 3 RCT



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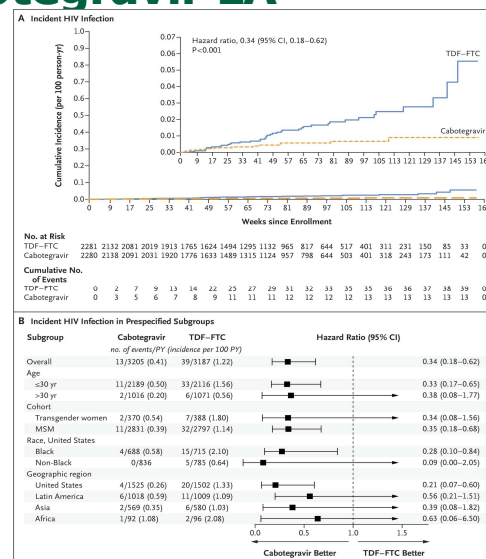
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HPTN 083 - Cabotegravir LA

- 52 Infections
 - 13 in CAB (0.41/100PY)
 - 39 in TDF (1.22/100PY)
- CAB *superior* to TDF/F
- OLE (Open Label Extension)
 - 46 additional incident HIV infections in extension
 - 4 while blinded (2 CAB, 2 TDF/F) and 42 after unblinding (11 CAB/31 TDF/F)
 - HR remains 0.33 – 0.34 – 66% Risk Reduction

Landovitz et al. NEJM 2021
Landovitz et al. CROI 2022



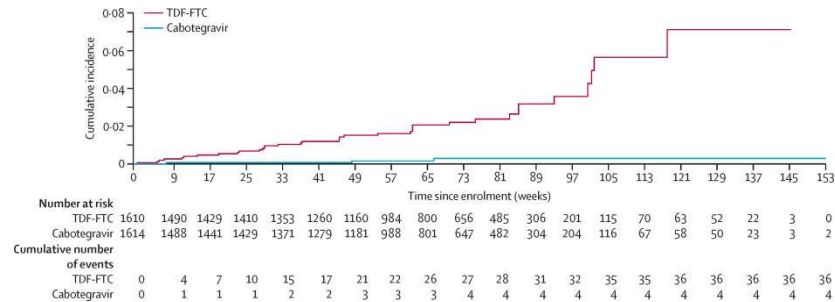
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HPTN 084 – Cabotegravir LA



- >3,000 cisgender women, Median Age: 25y
- 38 total infections:
 - 4 CAB (0.2 incidence rate)
 - 1 baseline, 3 incident HIV
 - 34 TDF/FTC (1.79 incidence rate)
- HR 0.11 (95% CI 0.04-0.32)
- 62% detectable drug in TDF/FTC

89% Risk Reduction

Delany-Moretlwe S, et al. Lancet 2022

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Table 5 Timing of Oral PrEP-associated Laboratory Tests

Test	Screening/Baseline Visit	Q 3 months	Q 6 months	Q 12 months	When stopping PrEP
HIV Test	X*	X			X*
eCrCl	X CrCl <60 then no TDF/F		If age ≥50 or eCrCl <90 ml/min at PrEP initiation	If age <50 and eCrCl ≥90 ml/min at PrEP initiation	X
Syphilis	X	MSM /TGW	X		MSM/TGW
Gonorrhea	X	MSM /TGW	X		MSM /TGW
Chlamydia	X	MSM /TGW	X		MSM /TGW
Lipid panel (F/TAF)	X^			X	
Hep B serology	X #				
Hep C serology	MSM, TGW, and PWID only			MSM, TGW, and PWID only	

* Assess for acute HIV infection (see Figure 4)

#Concern that stopping TDF or TAF in HBV+ could cause HBV to acutely flare

^ Lipids can increase on TAF

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CAB PrEP

Table 7 Timing of CAB PrEP-associated Laboratory Tests

Test	Initiation Visit	1 month visit	Q2 months	Q4 months	Q6 months	Q12 months	When Stopping CAB
HIV*	X	X	X	X	X	X	X
Syphilis	X			MSM ⁺ /TGW ⁻ only	Heterosexually active women and men only	X	MSM/TGW only
Gonorrhea	X			MSM/TGW only	Heterosexually active women and men only	X	MSM/TGW only
Chlamydia	X			MSM/TGW only	MSM/TGW only	Heterosexually active women and men only	MSM/TGW only

* HIV-1 RNA assay

No renal or lipid monitoring recommended currently

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The LEVI Syndrome

- Long-acting Early Viral Inhibition Syndrome

Comparison of acute HIV infection (AHI) to infections that occur in the setting of long-acting early viral inhibition (LEVI)

	AHI	LEVI
Cause	Phase of natural HIV infection	Long-acting anti-viral PrEP agent (prototype: CAB-LA)
Onset	New infection	Infection during PrEP Initiation of PrEP agent during acute/early infection
Viral replication	Explosive	Smoldering
Symptoms	Fever, chills, rash, night sweats, muscle aches, sore throat, fatigue, swollen glands	Minimal, variable, often no symptoms reported
Detection	Ag/Ab assay, RNA assays (including less sensitive POC and pooled tests), DNA assays, total nucleic acid assays	Ultrasensitive RNA assay (often low or undetectable RNA, low/undetectable DNA, diminished/delayed Ab production)
Assay reversion	Rare	Common for many test types
Duration	1-2 weeks (until Ab detection)	Months (until viral breakthrough, drug clearance, or ART start); can persist months after the anti-viral agent is discontinued
Transmission	Very likely	Unlikely (except possibly through blood transfusion)
Drug resistance	No (unless transmitted)	Yes (can emerge early when viral load is low)

Eshleman et al. CROI 2023

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PrEP Provision – Billing

- **Z29.81 – Encounter for HIV PrEP**
- **Z20.6: Contact with and (suspected) exposure to HIV**
- **Z20.2: Contact with and (suspected) exposure to infection with predominantly sexual mode of transmission**
- Z77.21: Contact with and (suspected) exposure to potentially hazardous body fluids
- **Z79.899: Other long-term drug monitoring**
- ~~Z72.5x: High Risk Sexual Behavior~~

Riddell J, Amico R, Mayer K. JAMA 2018

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Same Day PrEP Starts

- **Rapid HIV testing (Ag/Ab) – must have same day HIV result**
 - Prefer lab based if available same day but ok to use POC 4th generation
 - Oral testing should not be used in this context
- Collect lab-based HIV testing and creatinine monitoring
- Ensure reliable and rapid contact information for patient
- Should not be used if patient is
 - Cannot provide lab specimens
 - Suspicion for acute HIV
 - History of medically significant comorbidities (CKD)
 - Cannot provide reliable immediate contact info.

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Doxycycline Post-Exposure Prophylaxis

DoxyPEP



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1967
Years of Safety

95% oral
absorption

20h half-life
QD or BID

Interrupted by
calcium,
aluminum,
magnesium,
and iron

Doxy

Common &
Affordable

FDA Class D
Potential for
"brown teeth"

GI Upset
Esophagitis
Skin Reactions
Photosensitivity

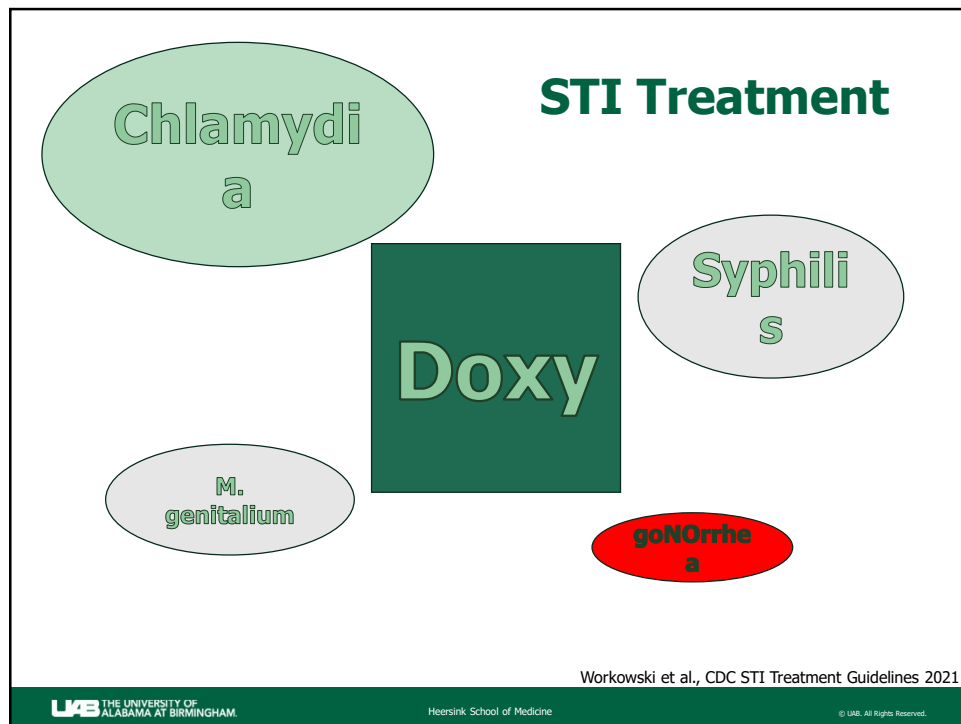
Few DDIs and
no dose change
in CKD



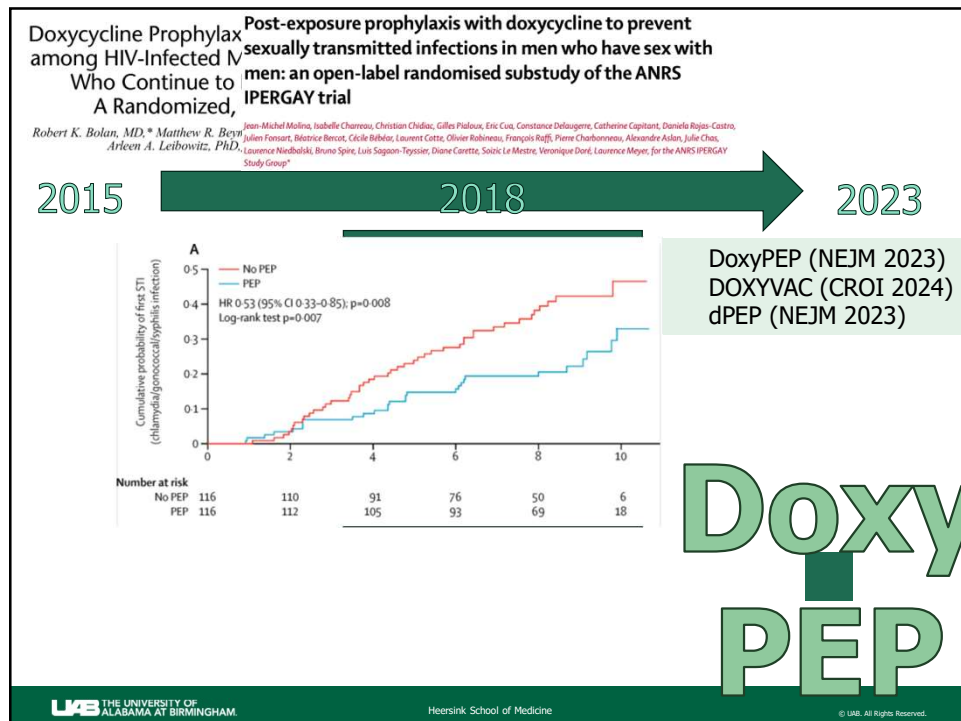
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Heersink. *Seminars in Medicine*. Pouriere et al. *J Antimicrob Chemother*. 2018. © UAB. All Rights Reserved.

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The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Postexposure Doxycycline to Prevent Bacterial Sexually Transmitted Infections

Anne F. Luetkemeyer, M.D., Deborah Donnell, Ph.D.,
Julia C. Dombrowski, M.D., M.P.H., Stephanie Cohen, M.D., M.P.H.,
Cole Grabow, M.P.H., Clare E. Brown, Ph.D., Cheryl Malinski, B.S.,
Rodney Perkins, R.N., M.P.H., Melody Nasser, B.A., Carolina Lopez, B.A.,
Eric Vittinghoff, Ph.D., Susan P. Buchbinder, M.D., Hyman Scott, M.D., M.P.H.,
Edwin D. Charlebois, Ph.D., M.P.H., Diane V. Havlir, M.D., Olusegun O. Soge, Ph.D.,
and Connie Celum, M.D., M.P.H., for the DoxyPEP Study Team*

Open-Label, 2:1 RCT
MSM & Transgender women
PLWH and PrEP
Recent Bacterial STIs

Doxycycline 200mg once
< 24-72 hours / encounter
Quarterly STI testing

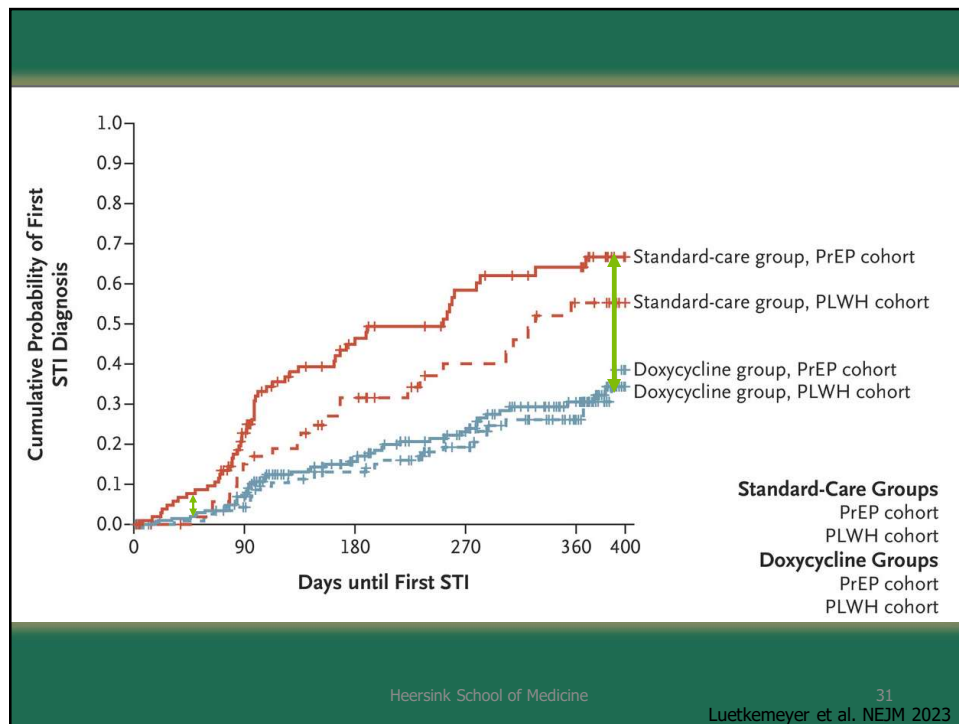
Luetkemeyer et al. N Engl J Med. 2023
doi: 10.1056/NEJMoa2211934. <https://www.nejm.org/doi/10.1056/NEJMoa2211934>

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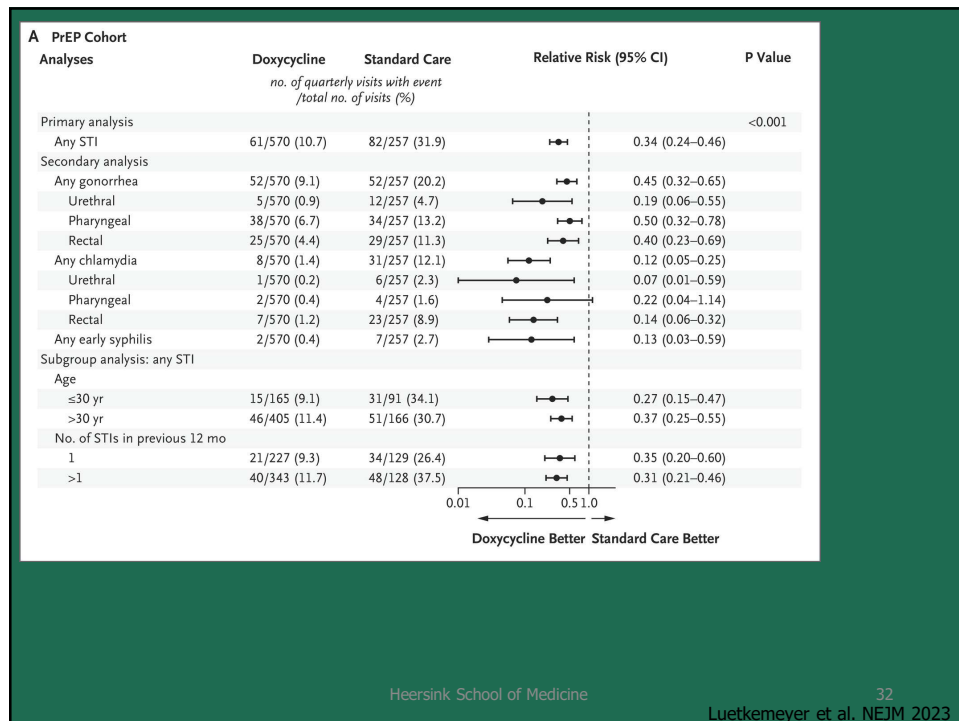
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Characteristic	PrEP Cohort		PLWH Cohort		Total (N=501)
	Doxycycline Group (N=220)	Standard-Care Group (N=107)	Doxycycline Group (N=119)	Standard-Care Group (N=55)	
Median age (IQR) — yr	36 (31–42)	36 (31–42)	43 (36–54)	42 (37–50)	38 (32–47)
Race — no./total no. (%)†					
White	144/209 (69)	66/104 (63)	74/116 (64)	37/53 (70)	321/482 (67)
Black	9/209 (4)	5/104 (5)	15/116 (13)	7/53 (13)	36/482 (7)
Asian or Pacific Islander	33/209 (16)	12/104 (12)	7/116 (6)	1/53 (2)	53/482 (11)
Multiple races or other	23/209 (11)	21/104 (20)	20/116 (17)	8/53 (15)	72/482 (15)
Hispanic or Latino ethnic group — no. (%)†	55 (25)	41 (38)	41 (34)	14 (25)	151 (30)
Gender identity — no. (%)					
Man	212 (96)	107 (100)	109 (92)	54 (98)	482 (96)
Transgender woman or gender-diverse	8 (4)	0	10 (8)	1 (2)	19 (4)
Gender of sexual partners — no./total no. (%)					
Men only	191/220 (87)	90/107 (84)	105/118 (89)	48/55 (87)	434/500 (87)
Multiple genders	29/220 (13)	17/107 (16)	13/118 (11)	7/55 (13)	66/500 (13)
Annual income — no./total no. (%)					
<\$20,000	31/219 (14)	13/106 (12)	42/119 (35)	17/55 (31)	103/499 (21)
\$20,001–\$50,000	64/219 (29)	39/106 (37)	40/119 (34)	22/55 (40)	165/499 (33)
\$50,001–\$75,000	43/219 (21)	14/106 (13)	22/119 (18)	3/55 (9)	86/499 (17)
>\$75,000	79/219 (36)	40/106 (38)	15/119 (13)	11/55 (20)	145/499 (29)
STI in the past 12 mo — no. (%)					
Gonorrhea	155 (70)	78 (73)	71 (60)	39 (71)	343 (68)
Chlamydia	144 (65)	63 (59)	58 (49)	27 (49)	292 (58)
Syphilis‡	32 (15)	16 (1)	35 (29)	17 (31)	100 (20)
Two or more STIs in the past 12 mo — no. (%)	106 (48)	44 (41)	39 (33)	26 (47)	215 (43)
Any STI at baseline — no./total no. (%)	65/219 (30)	27/106 (25)	34/114 (30)	20/55 (36)	146/494 (30)
Gonorrhea	40/218 (18)	20/107 (19)	25/117 (21)	14/54 (26)	99/496 (20)
Chlamydia	31/219 (14)	11/107 (10)	11/117 (9)	8/54 (15)	61/497 (12)
Syphilis	5/219 (2)	1/107 (1)	11/117 (9)	4/55 (7)	21/498 (4)
Median no. of sexual partners in the past 3 mo (IQR)	8 (4–17)	10 (5–16.5)	7 (3–18.5)	10.5 (3–20)	9 (4–17)
Transactional sex during lifetime — no./total no. (%)§	47/219 (21)	28/107 (26)	47/116 (41)	21/49 (43)	143/491 (29)
Substance use in the past 3 mo — no./total no. (%)					
Stimulants: methamphetamine, cocaine, or crack	51/216 (24)	22/107 (21)	50/117 (43)	23/53 (43)	146/493 (30)
Heroin or other opioids	2/216 (1)	1/107 (1)	9/117 (8)	2/53 (4)	14/493 (3)
Ecstasy, GHB, or ketamine	63/216 (29)	34/107 (32)	39/117 (33)	21/53 (40)	157/493 (32)
Amyl nitrates, also known as poppers	93/216 (43)	47/107 (44)	56/117 (48)	28/53 (53)	224/493 (45)
Marijuana	96/216 (44)	56/107 (52)	60/117 (51)	27/53 (51)	239/493 (48)

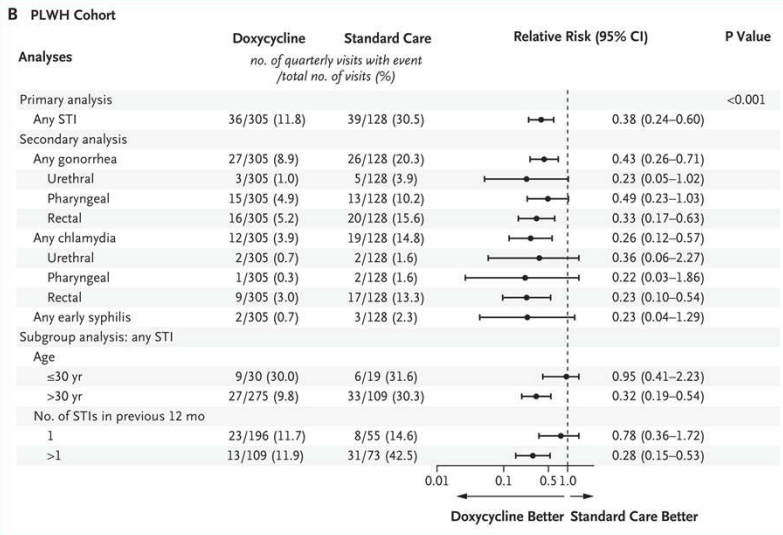
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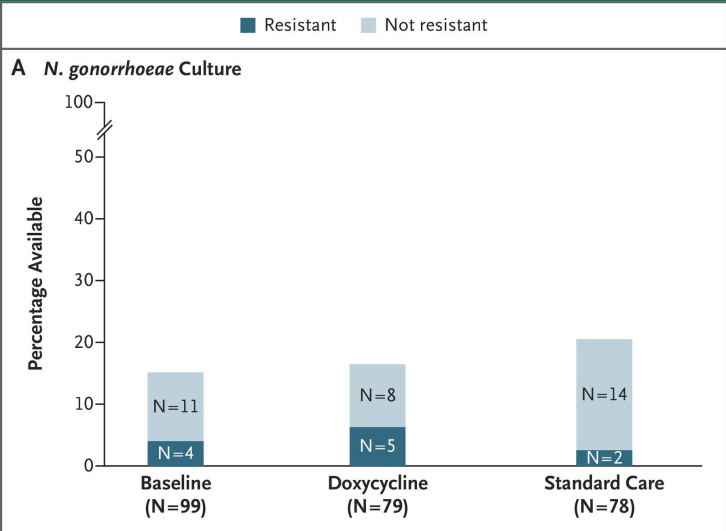
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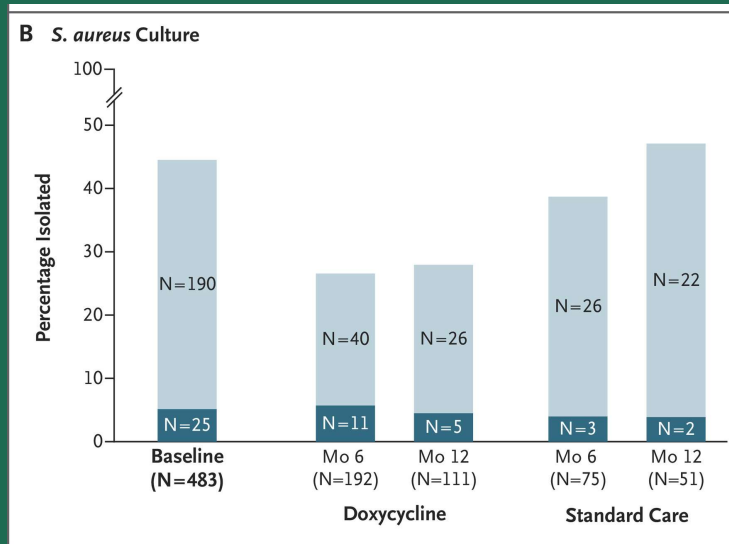
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GC Resistance

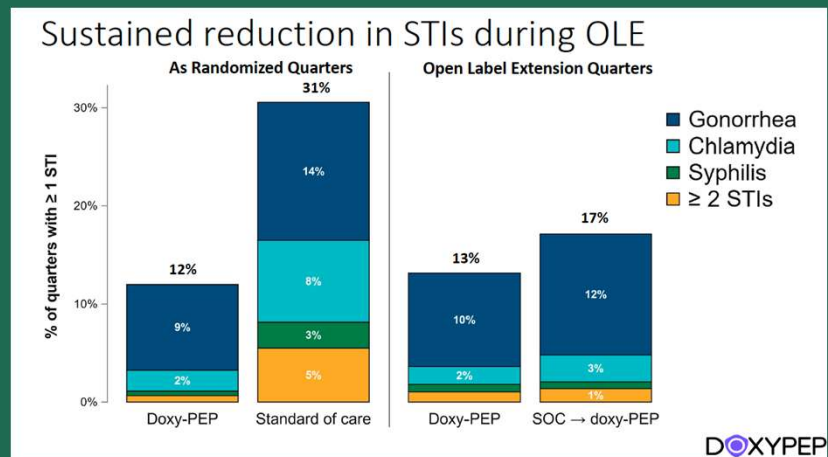
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Luetkemeyer et al. NEJM 2023

S. aureus TCN resistance

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DoxyPEP Open Label Extension



Luetkemeyer A, et al. Sustained reduction of bacterial STIs during the DoxyPEP study open-label extension. CROI 2024 (March 3-6, 2024, Denver. Abstract 125.

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Sexual behavior during OLE

median (IQR)	As-randomized		AR→OLE	
	doxy-PEP N quarters = 1077	SOC N quarters = 455	doxy-PEP N quarters = 388	SOC → doxy-PEP N quarters = 146
Doxy doses/quarter	15 (4-30)	—	17 (7-32)	17 (5-30)
Sex partners/quarter	10 (4-25)	8 (4-15)	12 (6-25)	16.5 (5-31)
Condomless insertive sex acts/quarter	5 (1-20)	4 (2-12)	8 (2-20)	8 (3-25)
Condomless receptive sex acts/quarter	8 (2-20)	5 (1-15)	10 (2-23.5)	10 (2-25)
% of condomless sex acts covered by doxy-PEP per quarter	82.4%	—	77.3%	81.3%

- **Sexual partners & condomless sex:** ↑ during OLE in both groups; doubled in SOC → doxy-PEP
- **Reported doxy-PEP coverage of condomless sex:** High (> 75%) during OLE; comparable to doxy-PEP AR

DOXYPEP

Luetkemeyer A, et al. CROI 2024. Abstract 125.

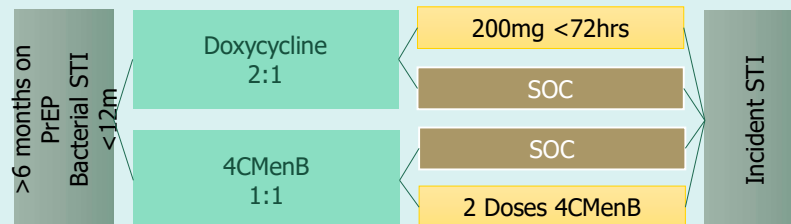
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DOXYVAC

- ANRS – French PrEP study, on-demand PrEP
- Open-label, randomized trial
- MSM on PrEP



Molina et al. CROI 2024

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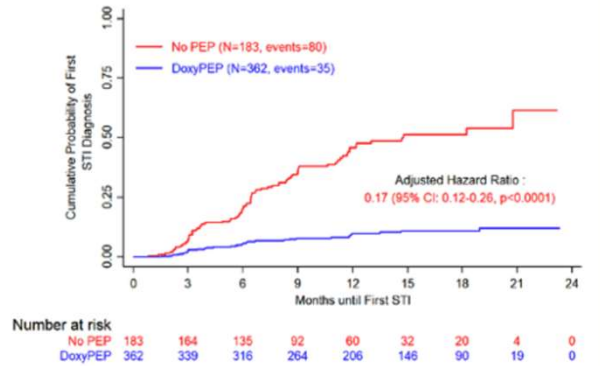
Doxycycline PEP Time to First CT or Syphilis Infection

No interaction between
Doxy PEP and 4CMenB
vaccine ($p=0.83$)

Median follow-up:
14 months (IQR: 9-18)

115 subjects infected
80 in No PEP arm
(incidence: 53.2/100 PY),
35 in Doxy PEP arm
(incidence: 8.8/100 PY)

Interim analysis:
49 subjects infected, aHR: 0.16



For CT multi-sites infection = 1 single event

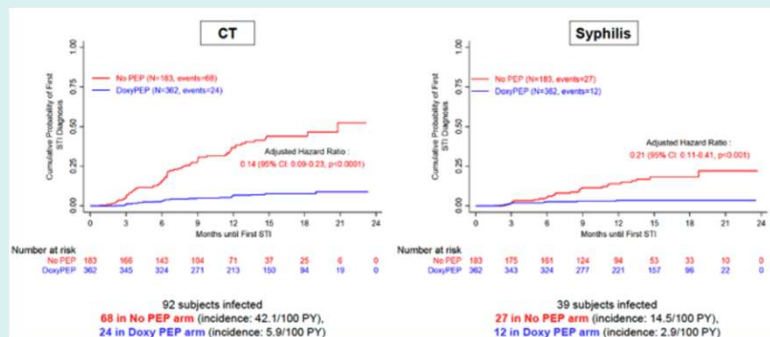
Molina et al. CROI 2024

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Significantly lower CT and syphilis each

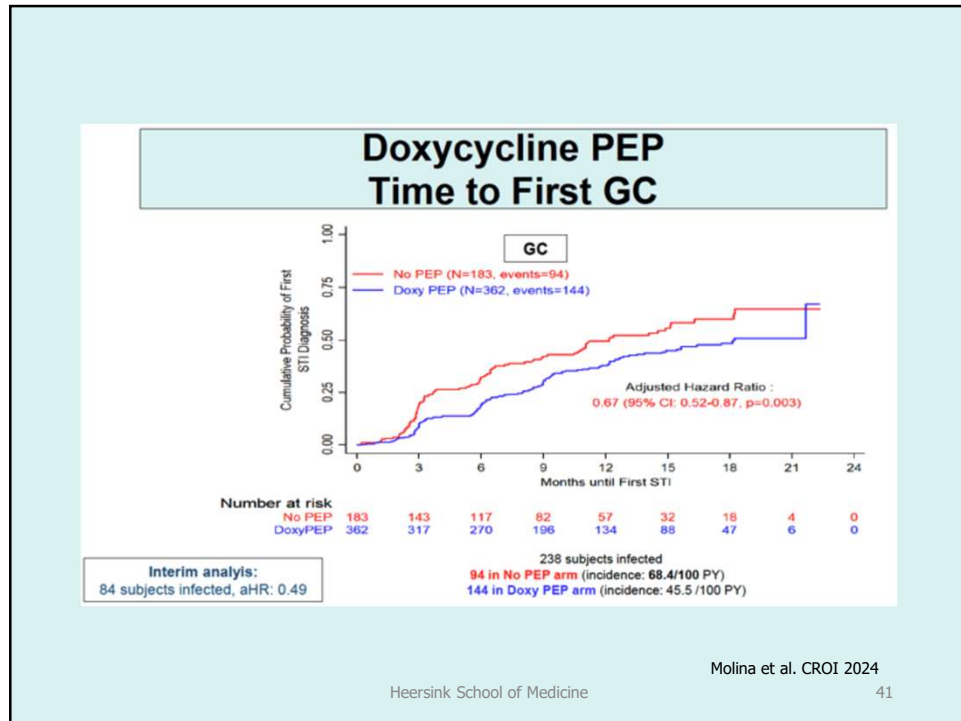


Molina et al. CROI 2024

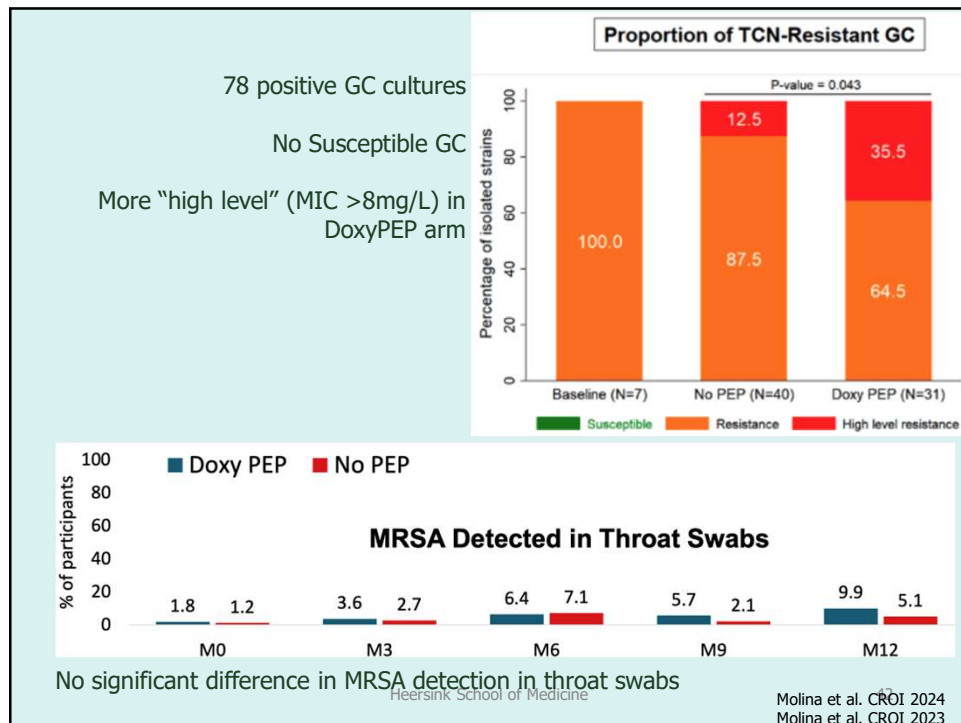
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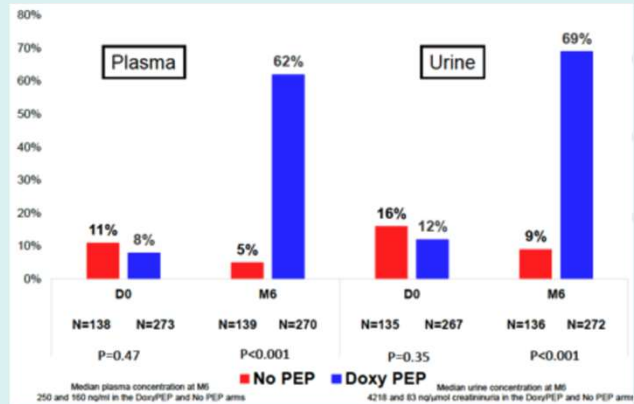


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Reasonably good adherence

Median time to PEP <24hrs

Median PEP at last sex act >70%



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dPEP Kenya

- Open-Label 1:1 Randomized Control Trial
- ~450 Cisgender Kenyan Women on PrEP
- Primary outcome was incident STI
- Median Age 24 years, 18% have STI at baseline

Stewart, J. et al., NEJM 2024 DOI:
doi:10.1056/NEJMoa2304007
<https://www.nejm.org/doi/full/10.1056/NEJMoa2304007>

Table 1. Demographic and Clinical Characteristics of the Participants at Baseline.^a

Characteristic	Doxycycline PEP (N=224)	Standard Care (N=225)
Median age (IQR) — yr	24 (22–27)	24 (22–27)
Highest level of education — no. (%)		
No schooling	1 (0.4)	0
Primary school	48 (21.4)	55 (24.4)
Secondary school	135 (60.3)	128 (56.9)
Postsecondary school	40 (17.9)	42 (18.7)
Earns own income — no. (%)	137 (61.2)	143 (63.6)
Marital status — no. (%)		
Never married	158 (70.5)	139 (61.8)
Married	39 (17.4)	53 (23.6)
Previously married	27 (12.1)	33 (14.7)
Has a primary sex partner — no. (%)	186 (83.0)	184 (81.8)
New sex partner in the previous 3 mo — no. (%)	77 (34.4)	72 (32.0)
Median no. of partners in the previous 3 mo (IQR)	2 (1–5)	2 (1–4)
History of transactional sex in the previous 3 mo — no. (%)	89 (39.7)	76 (33.8)
Condom use at last vaginal sex act — no./total no. (%) [†]	62/199 (31.2)	67/199 (33.7)
History of anal sex in the previous 3 mo — no. (%)	4 (1.8)	7 (3.1)
Median duration of HIV PrEP (IQR) — mo	7.5 (4.1–14.9)	7.2 (3.7–13.8)
Use of contraception — no. (%) [‡]	143 (63.8)	135 (60.0)
Parity — no. (%)		
None	72 (32.1)	65 (28.9)
1 live birth	89 (39.7)	83 (36.9)
≥2 live births	63 (28.1)	77 (34.2)
Presence of STI — no. (%)		
Chlamydia trachomatis [§]	30 (13.4)	33 (14.7)
Neisseria gonorrhoeae [§]	10 (4.5)	7 (3.1)
Treponema pallidum	0	2 (0.9)
Any STI [§]	40 (17.9)	40 (17.9)

^a Percentages may not total 100 because of rounding. HIV PrEP denotes preexposure prophylaxis against human immunodeficiency virus, IQR denotes interquartile range, PEP postexposure prophylaxis, and STI sexually transmitted infection.

[†] A total of 51 participants did not have vaginal sex in the 3 months before enrollment.

[‡] Contraception includes intrauterine device, implant, depot medroxyprogesterone acetate, and oral contraceptive pills.

[§] One participant without an endocervical swab collected at baseline was enrolled.

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dPEP-KE

	dPEP N=224	SOC N=225	RR (95% CI)
Any	50/854	59/886	0.88 (0.60-1.29)
CT	35/854	50/886	0.73 (0.47-1.13)
GC	19/854	12/886	1.64 (0.78-3.47)

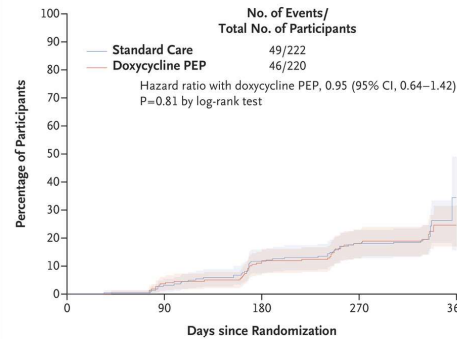
1 incident syphilis infection

80 Pregnancies

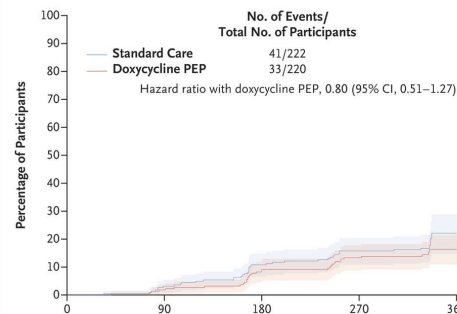
10.1% visits with doxycycline on hold

Stewart et al., NEJM 2023

A First Sexually Transmitted Infection



B First *C. trachomatis* Infection



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Adherence

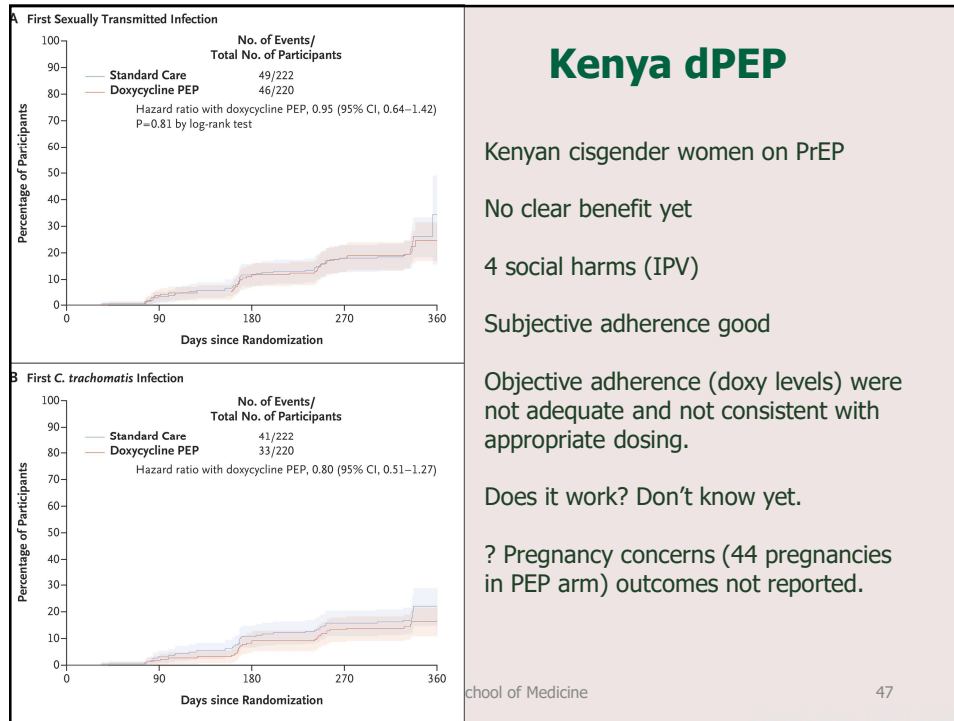
- 91% - completed quarterly timeline follow-back calendars
- 80% - Reported PEP event coverage in last 2 weeks
- 23.3% of visits reported not using PEP at last sex act
- 78% in dPEP group completed SMS surveys
- 55% reported taking PEP after their last sex act
- Among 50 dPEP hair samples
- 29% had detectable doxycycline in all visit
 - 33% when accounting for pregnancy hold visits
 - 6.7% had detectable at baseline, 5.1% in SOC arm

Stewart et al., NEJM 2023

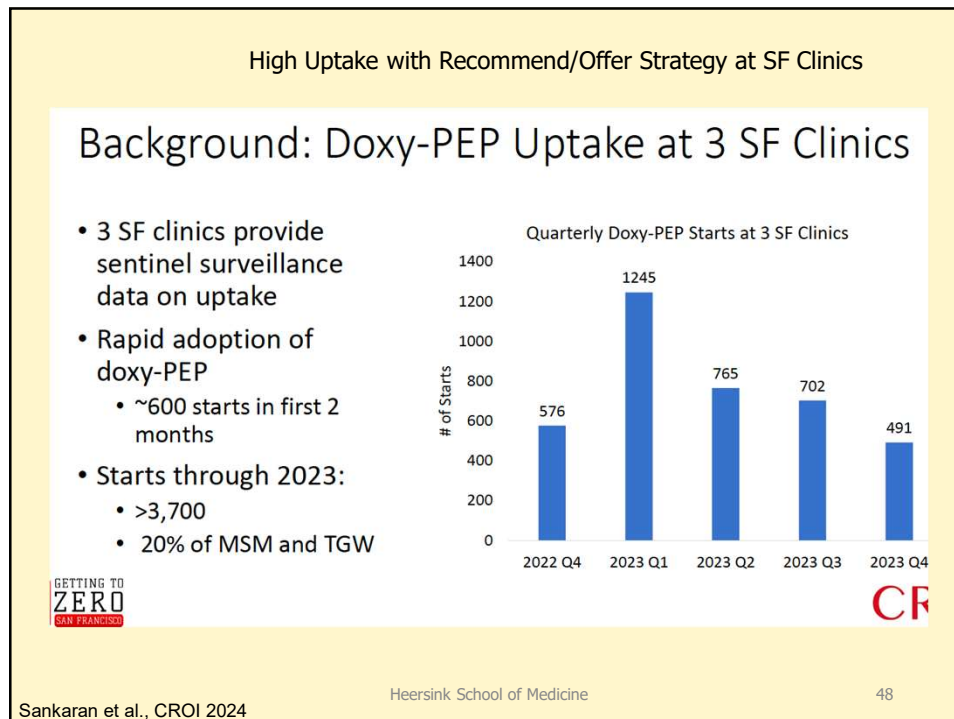
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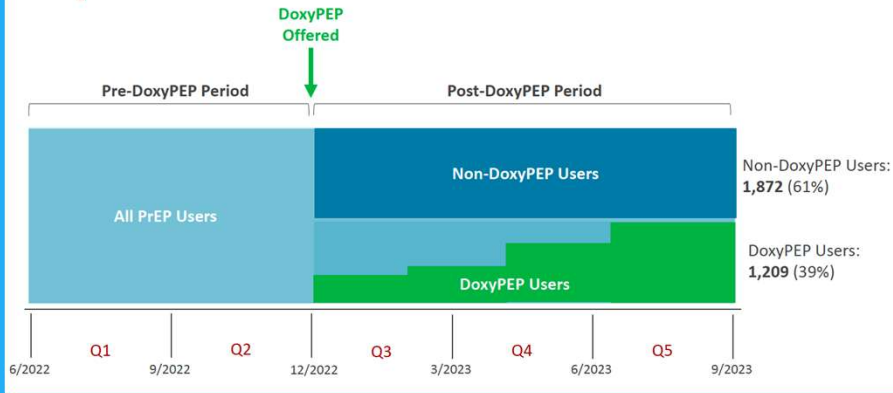
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DoxyPEP uptake at San Francisco PrEP Clinic

DoxyPEP Timeline

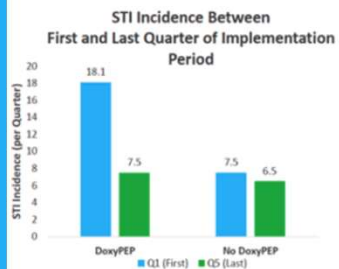


Scott H, et al. Doxycycline PEP: High uptake and significant decline in STIs after clinical implementation. CROI 2024, March 3-6, 2024, Denver. Abstract 126 [Heersink School of Medicine](#)

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Real world effectiveness

STI Incidence among DoxyPEP Users (Pre-Post Analysis)



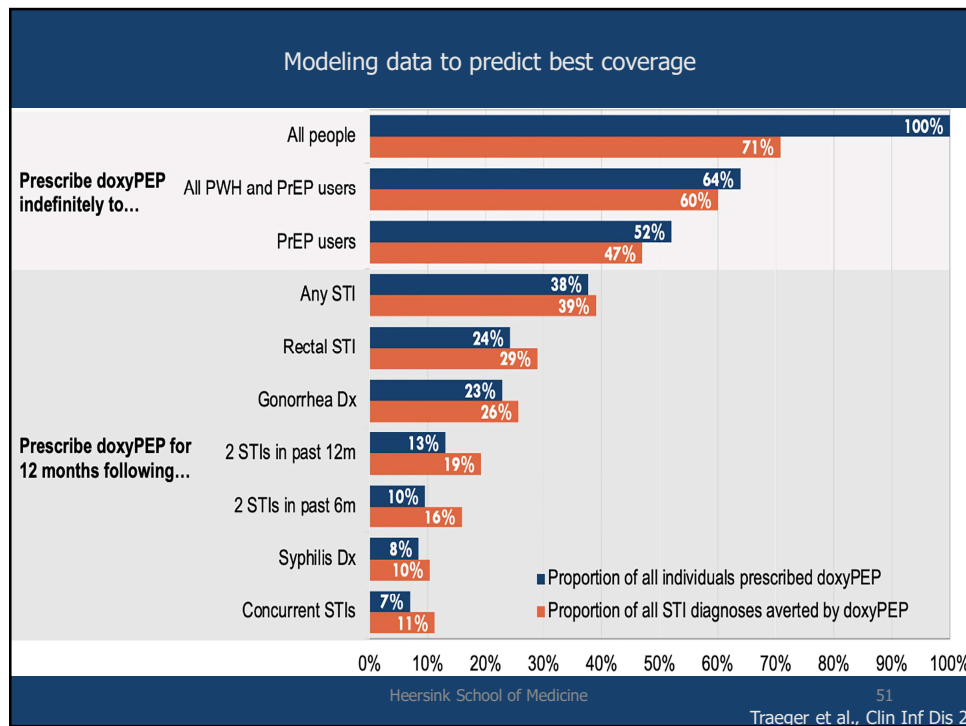
Any STI: Chlamydia, Syphilis, or Gonorrhea at any site.

	IRR	95% CI	p-value
Any STI	0.42	0.24 - 0.74	0.003
Chlamydia	0.33	0.23 - 0.46	<0.001
Syphilis	0.22	0.09 - 0.54	0.001
Gonorrhea	0.89	0.69 - 1.15	0.383

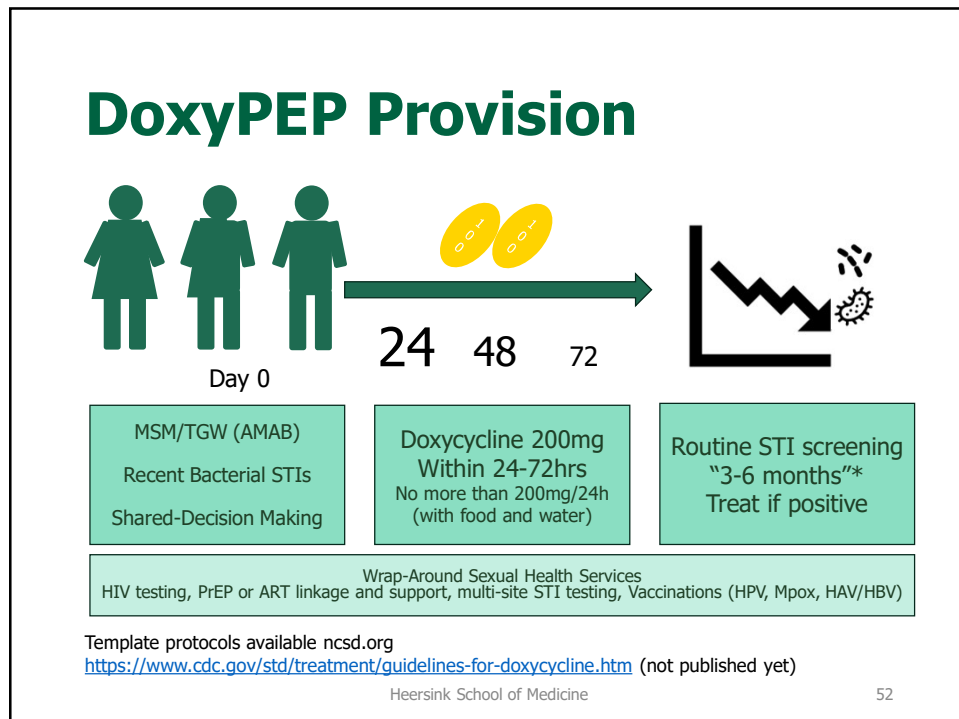
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Scott et al. CROI 2024

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Doxycycline PEP Concerns

- Antimicrobial Resistance
 - Questionable increase in gonorrhea AMR but no increase in *Staphylococcus aureus* TCN-resistance in DOXYPEP.
 - High-level GC Resistance in DOXYVAC already but no increase in TCN-resistance in *S. aureus*
- Microbiome disruption
 - DOXYVAC without significant changes in *E. coli*, used as a marker for gut microbiome
- Long-term data are not yet available
- Safety in persons who are/can be pregnant unknown

Luetkemeyer et al. NEJM 2023
Molina et al., CROI 2024
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Doxycycline PEP Summary

- Doxycycline as post-exposure prophylaxis is highly effective in GBM/TGW/AMAB
- DoxyPEP is safe
- Long term implications for antimicrobial resistance and microbiome are unknown, although short term data are reassuring
- More data are needed for effectiveness in persons assigned female sex at birth.

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Gratitude

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NIMH/NIH K23MH126794

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Questions?

Thank you!

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