

# Doxycycline PEP & Women

IAS Education Seminars  
7<sup>th</sup> May 2024

Felix Mogaka, MBChB, MPH  
Kenya Medical Research Institute

# Background:

---

Women eligible for HIV PrEP have high incidence of bacterial STIs

---

Untreated STIs can result in serious complications, esp in the uterus

---

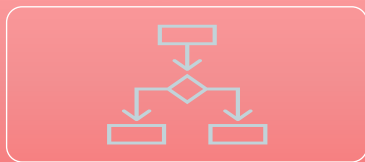
Doxycycline PEP effectively reduced incident STIs among cisgender men and TGW with high STI burden.

---

Among cisgender women, doxy-PEP did not reduce incident STIs in the dPEP Kenya Trial.



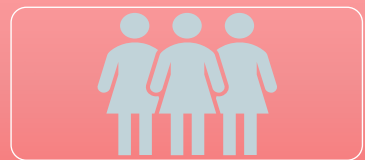
# dPEP Kenya Trial Study Design:



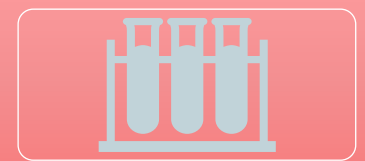
**Design:** Open-label 1:1 randomized trial

Intervention: 200mg doxycycline hyclate within 72 hours of sex

Standard of Care: Quarterly STI testing and treatment



**Population:** 449 nonpregnant cisgender women, aged 18-30, taking HIV PrEP, in Kisumu, Kenya during 2020-2022



**Approach:** Quarterly follow-up with STI (endocervical) NAAT testing and treatment. Weekly SMS surveys on frequency of sex and doxycycline use.



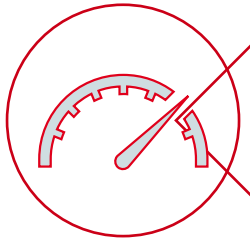
**Primary endpoint:** Any incident *C. trachomatis*, *N. gonorrhoeae*, or *T. pallidum* infection.

# IAS Results – Baseline Characteristics:

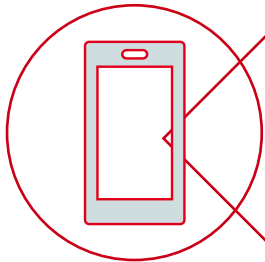
	Doxycycline PEP (N=224)	Standard of Care (N = 225)
Age, Median [IQR], years	24 [22-27]	24 [22-27]
Months on HIV PrEP, Median [IQR]	7.5 [4.1-14.9]	7.2 [3.7-13.8]
	% (n)	% (n)
Bacterial STI at baseline	18% (40)	18% (40)
<i>Chlamydia trachomatis</i>	13% (30)	15% (33)
<i>Neisseria gonorrhoeae</i>	5% (10)	3% (7)
<i>Treponema pallidum</i>	0% (0)	1% (2)

66% never married, 69% had prior pregnancies, 61% were using hormonal contraception, and 37% reported transactional sex

# Follow up of dPEP Kenya Trial participants:



97% of all quarterly follow-up visits were completed (95% PEP and 98% SOC).



Weekly SMS survey response rate of 81%.  
Women assigned to PEP reported event-driven dosing coverage in 78% of weekly SMS surveys.



80 pregnancies, 44 in PEP group and 36 in SOC group;  
Pregnancy holds of PEP accounted for 10% of follow-up time and other holds 5% follow-up time.



# STIs Incidence in the dPEP Kenya Trial:

Analysis	Endpoint	Total	PEP (N=224)	SOC (N=225)	RR	95% CI	P-value
Intention to Treat	All STIs	109	50	59	0.88	0.60-1.29	0.51
	Chlamydia	85	35	50	0.73	0.47-1.13	0.16
	Gonorrhea	31	19	12	1.64	0.78-3.47	0.19
Censoring Pregnancy Time	All STIs	105	48	57	0.91	0.62-1.35	0.65
	Chlamydia	82	33	49	0.73	0.46-1.15	0.18

Subgroup analyses of STI incidence by age, hormonal contraception use, transactional sex, and STI detected at baseline found similar results.

# Self-reported Adherence:

## Quarterly surveys

- 77% (579/755) coverage of last sexual exposure

## Timeline follow-back calendar

- In 72.8% of the quarterly surveys, >80% of sexual acts were covered

## Weekly SMS

- 64% (134/211) participants reported full coverage in at least 80% of weeks
- 78% of weekly SMS reported full coverage

# Adherence: Hair testing:

- The 1 cm hair segment from the scalp tested for doxycycline presence (represents exposure over approx. 1 month):
- Only 29.0% (58/200) of hair samples had doxycycline detected
- 32.6% (58/178) when censoring pregnancy time off doxycycline.





# Interpretation of dPEP Kenya Trial Results:

## Anatomy:

- Endocervical tissue differs from urethral, rectal, and pharyngeal tissues.

## Resistance:

- No documented cases of resistant *C. trachomatis* globally
- 100% doxycycline resistant *N. gonorrhoeae* in Kenya

## Adherence:

- Hair drug testing with low use of doxycycline
- event-driven adherence cannot be measured objectively

# Discussion:

- Doxycycline for STI prevention might still work for women
  - Additional trials of doxycycline PEP/PrEP for women are needed
  - Focus on effectiveness, but also acceptability & self-efficacy
  - Better understanding of barriers and facilitators to adherence to support use

# IAS **Next Steps: ongoing and planned studies**

## **Weekly doxycycline directly observed therapy:**

- Rationale: 200mg of doxyPEP might provide prevention coverage for ~4 days in
- Population: 50 participants, Western Kenya
- Duration: 6 months
- Results expected Mid 2025

*Investigators: Jared Baeten (PI) Elizabeth Bukusi (PI), Jenell Stewart (Director)*

## **DoxyPEP effectiveness among people assigned female sex at birth:**

- Rationale: Inconclusive evidence on doxyPEP efficacy; different setting
- Population: People AFAB in the US
- Duration: 12 months
- Results expected: 2028

*Investigators: ATN, Cherie Blair, Jenell Stewart*

# IAS Acknowledgements:

IAS Educational Series

dPEP Kenya Trial Participants

dPEP Kenya Trial Team

NIH: R01AI145971, P30AI027757, K23MH124466, 3R01AI098472



UNIVERSITY OF WASHINGTON  
INTERNATIONAL CLINICAL RESEARCH CENTER



JMB is an employee of Gilead Sciences outside of the presented work.