

DoxyPEP Implementation

All Systems Go?



Welcome!



October 5, 2023
9 to 10:30 AM Eastern



HIV prevention research - a new forum
for advocacy on the latest

avac.org/project/choice-agenda



**Thank you
National Coalition
of STD Directors for
partnering with
The Choice Agenda
on this webinar.**



A snapshot of audience HOPES

- A new tool
- Decrease overall rates of STIs
- Possibility of reducing long term sequelae of untreated STIs
- More independence and autonomy for clients
- Sexual freedom and pleasure
- Less anxiety/worry for folks
- Accessible and affordable, low cost
- Could help reduce associated HIV infections
- Safe and effective

Thank you to the 566 registrants from 39 countries who shared their questions, hopes and concerns about DoxyPEP.

A snapshot of audience CONCERNS

- Access, rural access, access for people of color and people who are not gay/bi men
- If we start marketing to just gay/bi men, will this limit uptake among other groups?
- Adverse reactions, side effects, safety
- Resistance
- Funding, cost
- How effective?
- What about breakthrough infections?
- Provider willingness
- Homophobia and stigma related to sexual behaviors

Thank you to the 566 registrants from 39 countries who shared their questions, hopes and concerns about DoxyPEP.

**American
Samoa**

Argentina

Belgium

Bolivia

Botswana

Brazil

Burkina Faso

Canada

Colombia

Côte d'Ivoire

Eswatini

Gambia

Guinea

India

Italy

Jamaica

Kenya

Malawi

Mongolia

Mozambique

Namibia

Nigeria

Peru

Philippines

Rwanda

Senegal

**South
Africa**

**South
Sudan**

Spain

Switzerland

Tanzania

Thailand

Uganda

Ukraine

**United
Kingdom**

**United
States**

Yemen

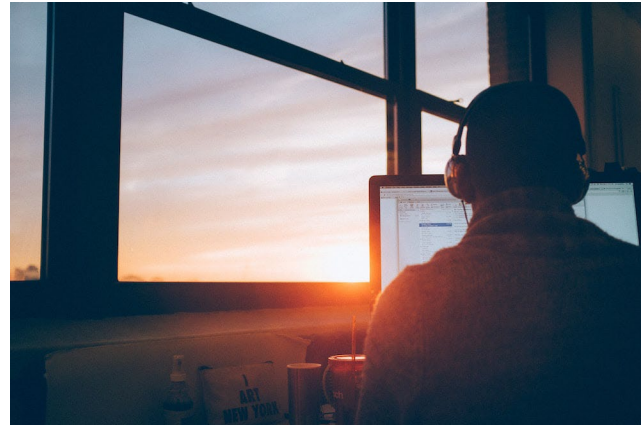
Zambia

Zimbabwe

DoxyPEP
All Systems Go?

Playlist

- **Give Me a Reason**
Sonny Fodera & Janai
- **Sex & The City, feat. Paul Johnson**
HoneyLuv & Seth Troxler
[MK Remix]
- **Pape Ndiaye**
Orchestra Baobab
- **White Rabbit**
Jefferson Airplane
- **Feels So Good**
Arielle Free



HIV prevention research - a new forum
for advocacy on the latest

Wednesday November 15
10 AM - 11:30 AM ET

HPTN 096: Building Equity Through Advocacy

**An Integrated, Status-Neutral, Approach for
Ending the Epidemic Among Black Gay Men in the South**

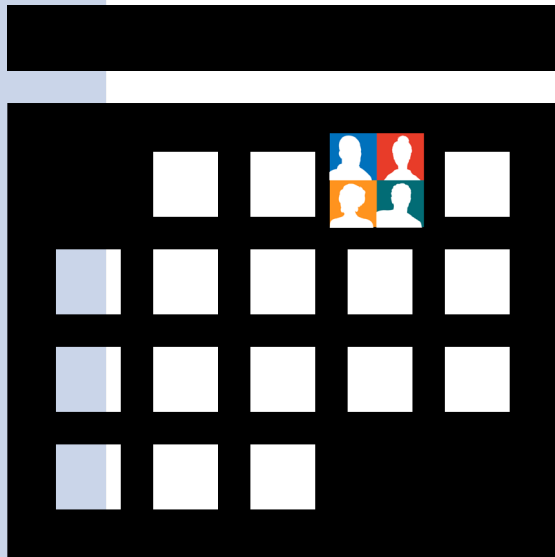
**Register for the webinar here:
tinyurl.com/buildingequitythroughadvocacy**



**co-sponsors:
PrEP in Black America
Federal AIDS Policy Partnership Research Working Group**

Save the date

November 2, 9 AM ET



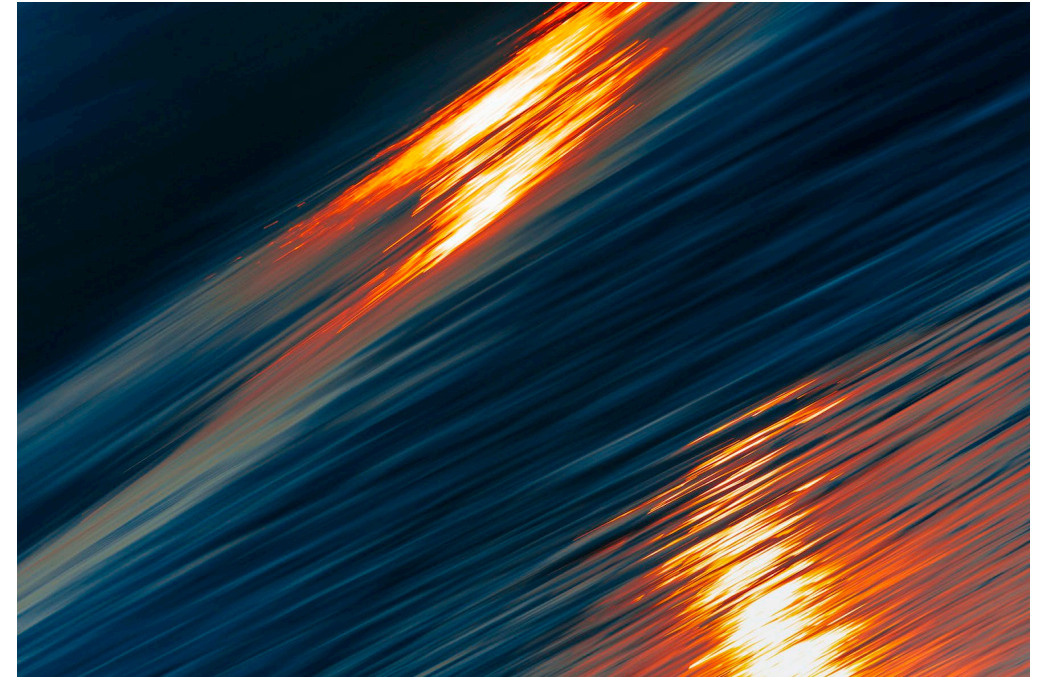
Webinar on decolonization of
global public health

Collaboration with
O'Neill Institute for
National and Global Health Law

5 October Agenda

Webinar speakers:

- **Lee Vaughn-Ogin**
Bigger Blacker Book, DoxyPEP consumer
- **Dr. Taimur Khan**
Fenway Health
- **Kendrick Clack, NP**
Crofoot MD Clinic/Research Center
- **Cait Shea**
National Coalition of STD Directors



**DoxyPEP Implementation
All Systems Go?**



THE FENWAY INSTITUTE
FENWAY  HEALTH



DoxyPEP: From Data To Implementation

TCA/NCSD Webinar | 5-October-2023

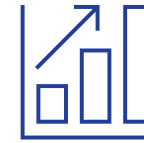
Taimur H. Khan MD MPH

Internal Medicine & Infectious Diseases | Fenway Health
Associate Medical Research Director | The Fenway Institute

thefenwayinstitute.org

DoxyPEP: Agenda

STI Trends



DoxyPEP Studies



Gaps In The Data



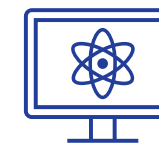
Fenway Health



Special Considerations



National Guidance



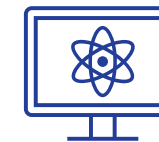
DATA

IMPLEMENTATION

DoxyPEP: STI Trends



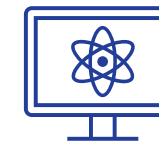
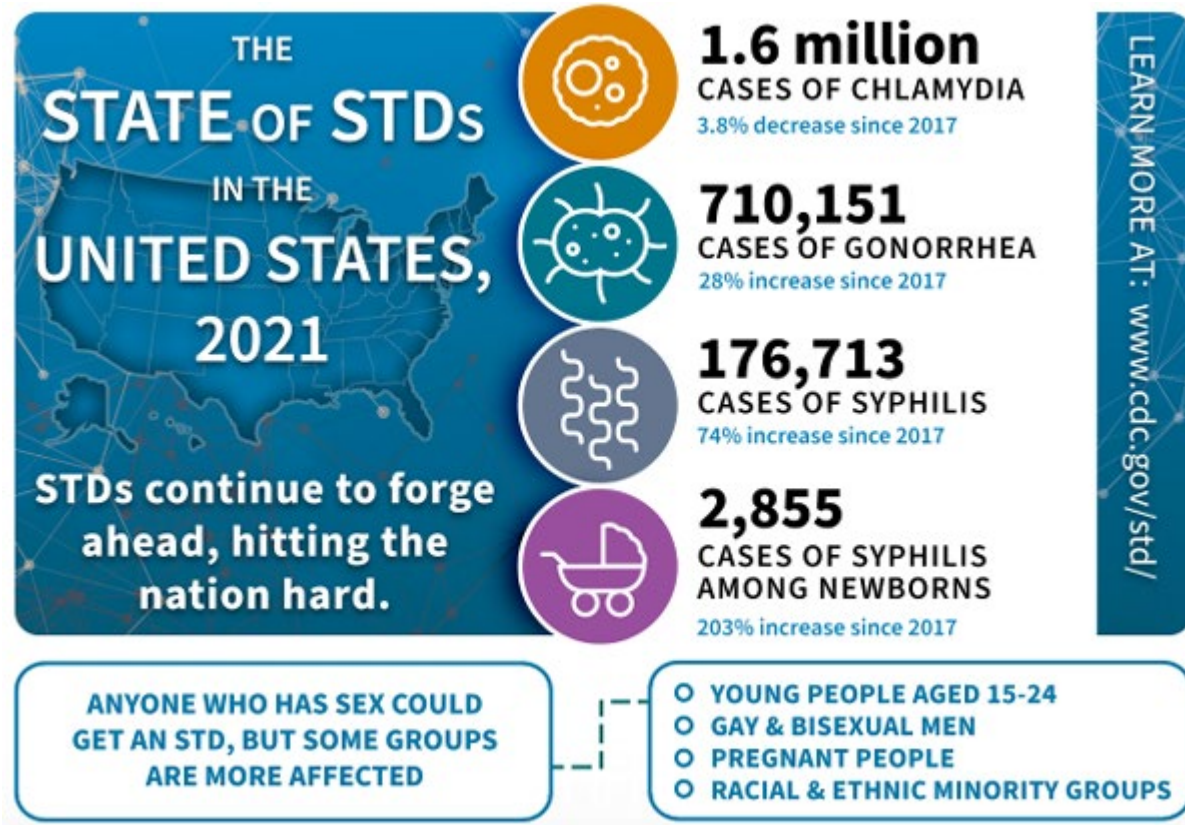
WHO Global Progress Report 2021



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DoxyPEP: STI Trends

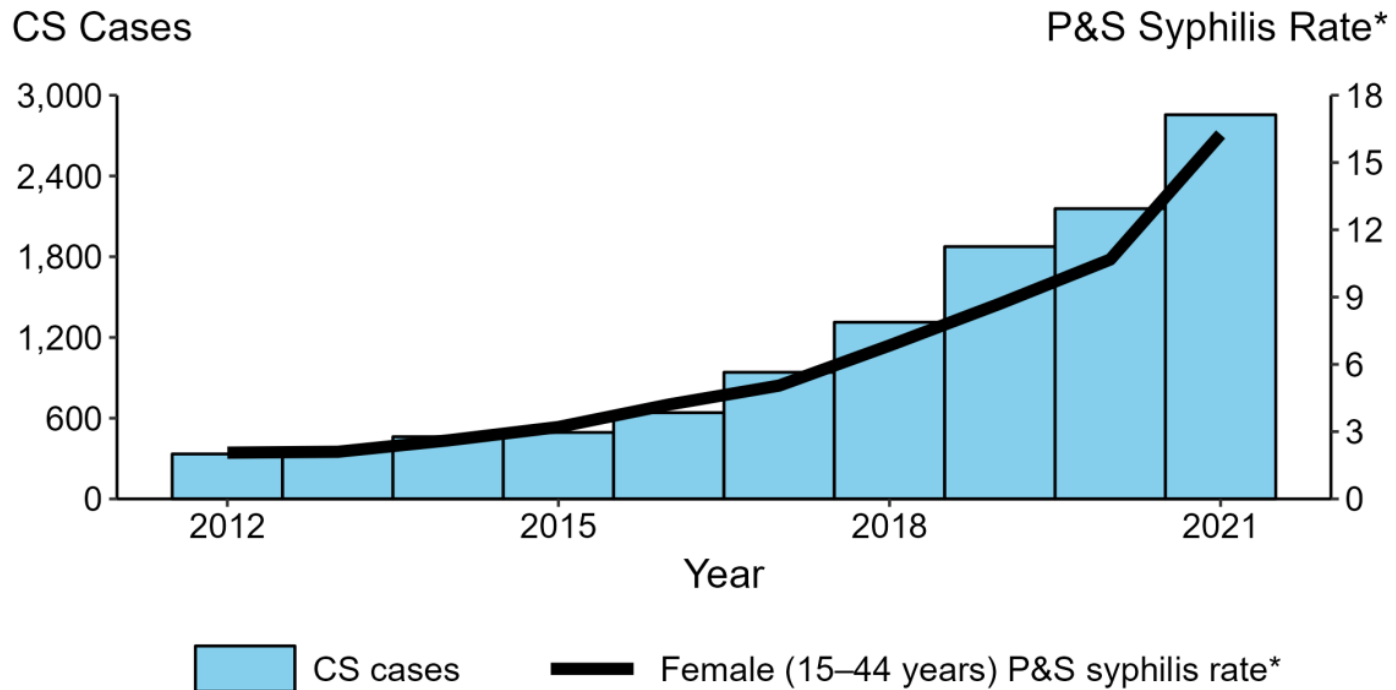


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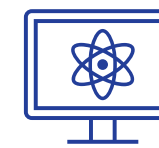
DoxyPEP: STI Trends

Congenital Syphilis — Reported Cases by Year of Birth and Rates of Reported Cases of Primary and Secondary Syphilis Among Women Aged 15–44 Years, United States, 2012–2021



* Per 100,000

ACRONYMS: CS = Congenital syphilis; P&S Syphilis = Primary and secondary syphilis



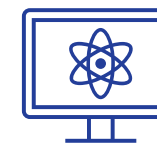
DATA

IMPLEMENTATION

DoxyPEP: DoxyPEP Studies

Doxycycline as Post-Exposure Prophylaxis

- Safe, well tolerated, inexpensive
- Active against **chlamydia** (CT) and **syphilis**
- Some resistance to **gonorrhea** (GC)
 - 20% of isolates in the US
 - Not 1st line treatment



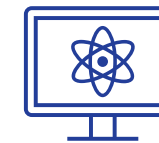
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DoxyPEP: DoxyPEP Studies

2015 - 2018

IPERGAY French PrEP-On-Demand Study includes Doxycycline as PEP, reveals 2/3 reduction in syphilis and chlamydia in MSM; but was not effective for gonorrhea.



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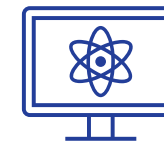
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2022 - 2023

DOXYPEP Study by Luetkemeyer *et al* shares data at AIDS 2022 and with NEJM 2023



DATA

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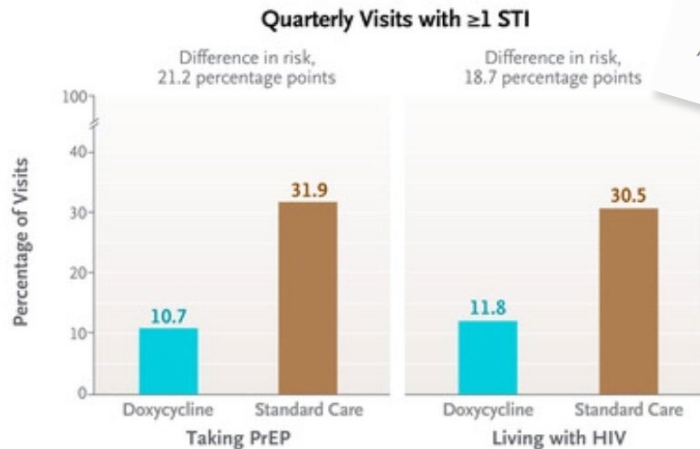
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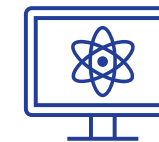
Postexposure Doxycycline to Prevent Bacterial Sexually Transmitted Infections

Anne F. Luetkemeyer, M.D., Deborah Donnell, Ph.D., Julia C. Dombrowski, M.D., M.P.H.,
Stephanie Cohen, M.D., M.P.H., *et al.*, for the DoxyPEP Study Team*



CONCLUSIONS

Among MSM and transgender women who had recently had a bacterial STI, doxycycline postexposure prophylaxis was associated with a lower risk of bacterial STIs than standard care.



DATA

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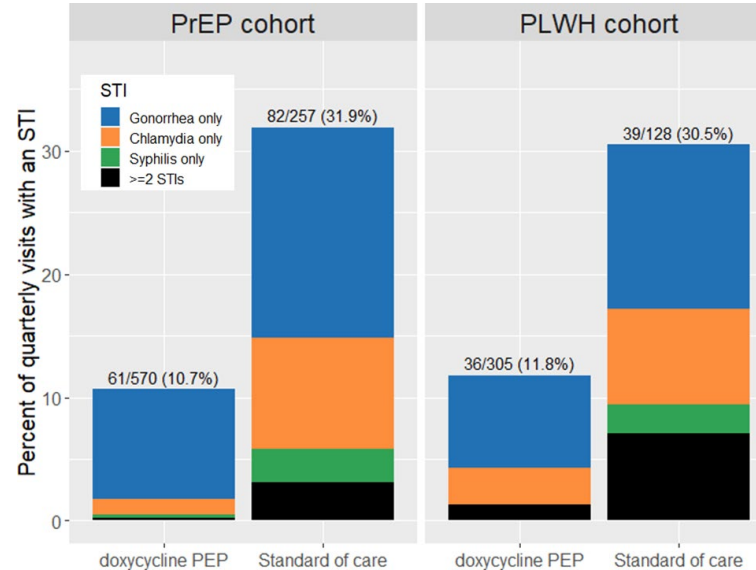
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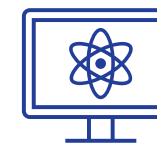
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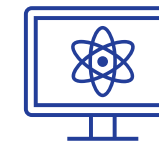
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DATA

IMPLEMENTATION

DoxyPEP: Gaps In The Data

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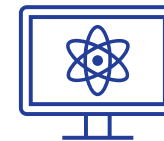
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2023

DOXYVAC Study, Molina *et al* CROI 2023

DPEP Study, Stewart *et al*, CROI 2023

Abstract [Mucosal Testing], Haaland, CROI 2023



DATA

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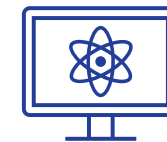
DoxyPEP: Gaps In The Data



Doxycycline PEP for Prevention of STIs among Kenyan Women on HIV PrEP

- 1:1 open-label randomized trial of dPEP (200mg doxycycline) taken within 72 hours after sex
- N=449 women taking PrEP, aged 18-30 (median age: 24 years)
- Quarterly follow-up for 12 months in Kisumu, Kenya

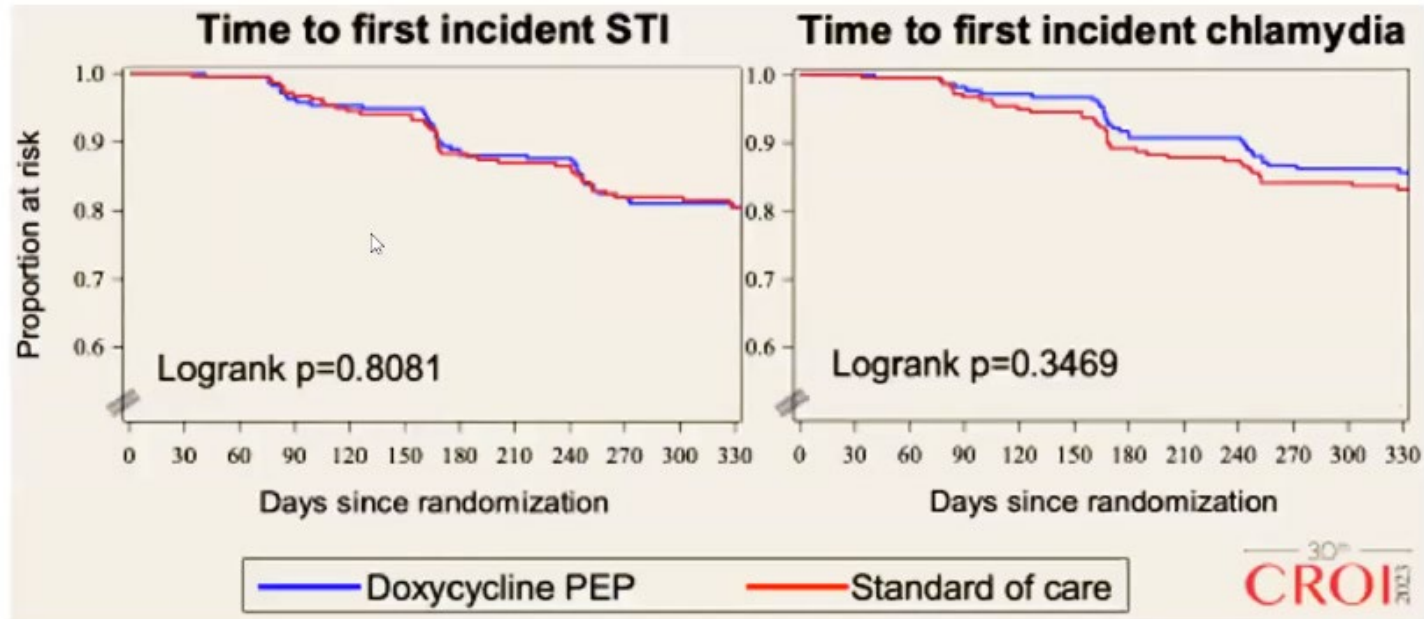
DPEP Study, CROI 2023



DATA

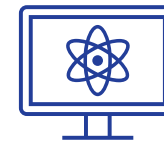
IMPLEMENTATION

DoxyPEP: Gaps In The Data



NO difference between the two arms

DPEP Study, CROI 2023



DATA

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DoxyPEP: Gaps In The Data

High 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

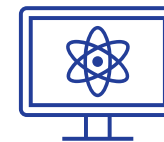
- 64% (134/211) participants reported full coverage in at least 80% of weeks
- 78% of weekly SMS reported full coverage

Doxy Hair testing: 44% assigned to doxy-PEP never had doxycycline detected

Results: Hair drug testing

- In a randomly selected subset of 50 participants assigned to doxycycline PEP
 - 56.0% (28/50) of participants had doxycycline detected at least once
 - 29.0% (58/200) of all quarterly visits had doxycycline detected,
 - 32.6% (58/178) when medication holds excluded
- 6.7% (3/45) of enrollment visits had doxycycline detected
- 5.1% (2/39) of follow up visits among SOC group had doxycycline detected

Stewart et al DPEP ISSTD 7.2023
DPEP Study, CROI 2023

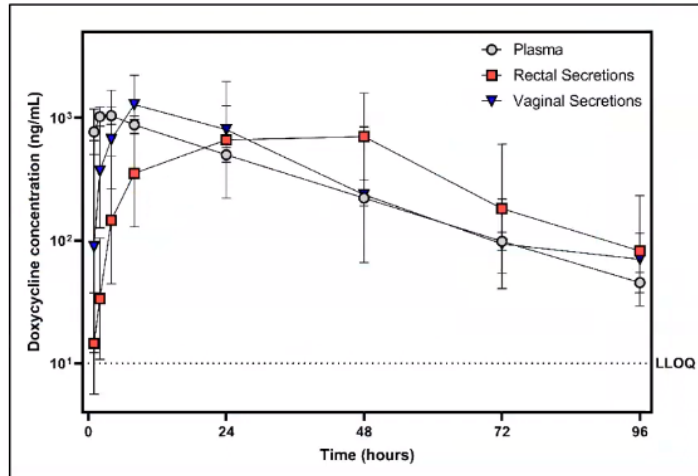


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DoxyPEP: Gaps In The Data

Mucosal Doxycycline Concentrations



Minimum Inhibitory Concentrations (MIC):

N gonorrhoeae (NG) MIC = 250 ng/mL CDC Antimicrob Resist Susc Test

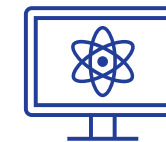
T pallidum (TP) MIC₉₀ = 100 ng/mL Edmondson *Antimicrob Agents Chemother* 2020

C trachomatis (CT) MIC₉₀ = 64 ng/mL Zheng *Sex Transm Dis* 2015

	<i>C trachomatis</i>		<i>T pallidum</i>		<i>N gonorrhoeae</i>	
	C _{max} *	Time >4x MIC	C _{max} *	Time >4x MIC	C _{max} *	Time >4x MIC
Plasma	16x	44h	10x	32h	4x	3h
Rectal Secretions	11x	62h	7x	51h	3x	NA
Vaginal Secretions	20x	45h	12x	38h	5x	11h

*Fold above MIC

Haaland CROI 2023,
abstract 118



DATA

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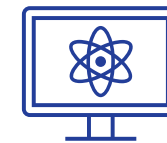
DoxyPEP: Gaps In The Data



Gonococcal Antibiotic Resistance?

- Limited information in these studies given the low numbers of isolates in each cohort.
- There is no data thus far to suggest that DoxyPEP is a driving for worsening ABX resistance, as TCN-Resistance is already significant with GC
- It is challenging to tease out what TCN-Resistance is due to exposures outside of DoxyPEP

Exposure to Ceftriaxone would decrease by 50%!



DATA

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DoxyPEP: Gaps In The Data



Gonococcal Antibiotic Resistance?

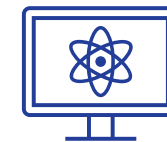
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Exposure to CTX would decrease by 50%!



Chlamydia & Syphilis Antibiotic Resistance?

- It has not clinically been documented. Testing for STI resistance is very difficulty with these pathogens, and would be expensive and very involved



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DoxyPEP: Gaps In The Data



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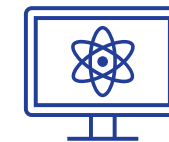
Chlamydia & Syphilis Antibiotic Resistance?

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Changes in Microbial Flora?

- Limited data on Staphylococcus and MRSA changes, no significant changes noted with the use of DoxyPEP at this time
- Gut Flora?



DATA

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DoxyPEP: Fenway Health



Boston, Massachusetts, USA
Federally Qualified Healthcare Center, Founded 1971

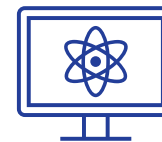
Our Mission

To enhance the wellbeing of the LGBTQIA+ community as well as people in our neighborhoods and beyond through access to the highest quality health care, education, research, and advocacy

Currently serving approximately 35,000 patients, with approximately 2,200 PLHIV.

The Fenway Institute

- Research, Education, Policy
- Involved in NIH-funded HIV Prevention Research along with Harvard/Boston/Providence centers

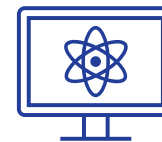


DATA

IMPLEMENTATION

DoxyPEP: Fenway Health

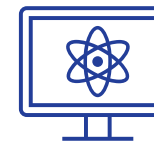
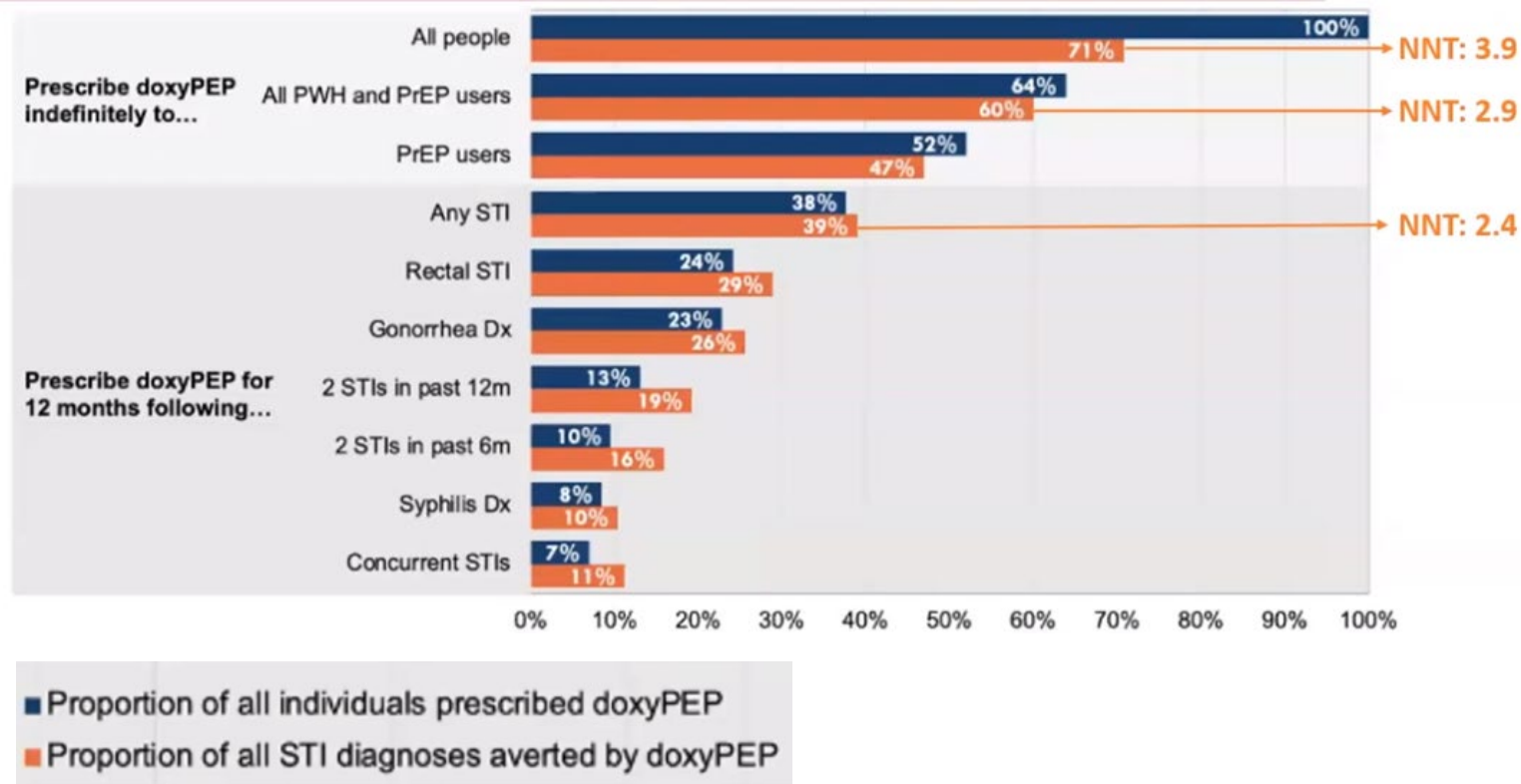
CDC/NACCHO Funded Implementation



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DoxyPEP: Fenway Health Traeger et al, 2022



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DoxyPEP: Fenway Health

DoxyPEP, Initial Conversation

Discussed role of Doxy PEP in preventing bacterial STIs.

Conversation was started by:

Patient meets risk based on:

- Assign Male At Birth, ≥ 18 yo

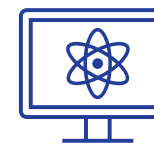
- plus -

FH DoxyPEP ▾

Patient FH Agree/doesnot agree ▾ to utilize DoxyPEP.

- A diagnosis of a bacterial STI in the last 12 months
- PrEP Use, 2 or more sexual partners with condomless oral/anal sex
- PLWH, 2 or more sexual partners with condomless oral/anal sex
- Shared decision making

What about AFAB (Assigned Female At Birth) patients?



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DoxyPEP: Fenway Health

Exposure to sexually transmitted disease (STD)

[Details](#) Chronic: ⓘ Code: Z20.2 Noted: 2/2/2023

🏠 **Outpatient**

✓ doxycycline (Vibramycin) 100 MG capsule
👉 🕒 Take 2 capsules (200 mg) by mouth if needed (within 72 hours of sexual activity). Take with at least 8 ounces (large glass) of water, do not lie down for 30 minutes after
Normal, Disp-50 capsule, R-1

ⓘ doxycycline (Vibramycin) 100 MG capsule
↑ Single dose of 200 mg exceeds recommended maximum of 100 mg by 100%
↑ Duration of 90 days exceeds recommended maximum of 30 days

DoxyPEP, Follow-up
Doing well on DoxyPEP.
Patient adverse side effects.
Known STD exposure(s):
Number of times DoxyPEP was utilized since last STI Testing Panel:

Patient meets high-risk criteria for benefiting from Doxycycline for Post-Exposure Prophylaxis (DoxyPEP) for CT/GC/Syphilis.

- Discussed data which supports prevention of chlamydia and syphilis, with limited data on Gonorrhea and ABX resistance.
- Rx'ed Doxy PO 200mg once within 72 hours of sexual activity (#50 RF1)
- Follow up in 3 months



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DoxyPEP: Fenway Health

What is it for?

To help prevent getting chlamydia, syphilis and gonorrhea. It is not 100% protective - but early data suggests it can decrease numbers by 60%!

How do I take it? "3-2-1"

3 - within 3 days or 72 hours

2 - take 2 tabs (or 200mg)

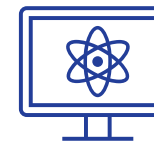
1 - once (limit to 1 time in one day)

- Take Doxycycline 100mg x 2 tabs (200mg together) once within 72 hours of possible exposure / risk - such as condomless oral/anal sex. It is better to take it within the first 24 hours.
- Do not take more than 200mg in one day. It is safe to take daily.
- Take with 8 oz of water and food if possible to help decrease any side-effects

Other important things to consider:

- We are still learning about the effects of DoxyPEP on "good" bacteria of the gut, changes to the bacteria that live on our skin (for example staph), and possible changes in resistance to STIs such as gonorrhea.
- Although doxycycline has been used for decades, there has been no resistance to doxycycline in chlamydia or syphilis.
- If you are having symptoms of an STI, come in to get tested and treated - otherwise continue your routine testing every 3 months.
- Doxycycline is not advised for persons that are pregnant/breastfeeding.

We may reach out to you through MyChart at some point in the next few months to see how your experience with DoxyPEP has been going. This helps us to learn, make changes, and help others.



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DoxyPEP: Fenway Health

Patients prescribed DoxyPEP at Fenway Health, by Age



■ 18-29 ■ 30-39 ■ 40-49 ■ 50-59 ■ 60+

Patients prescribed DoxyPEP at Fenway Health, by Race

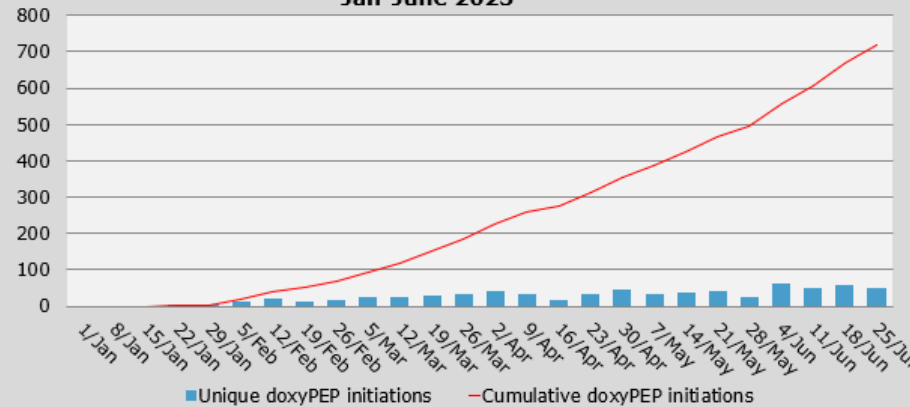


■ White ■ Black or African American ■ Asian ■ Other

Hispanic, Latinx – 15.6%
PrEP user (at end of follow-up) – 73.9%
 Living with HIV (at end of follow-up) – 8.8%

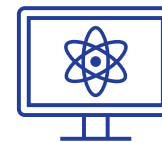


Cumulative DoxyPEP initiations at Fenway Health, Jan-June 2023



• Thus far, 719 patients have received a DoxyPEP prescription.

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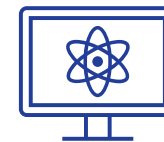


IMPLEMENTATION

DoxyPEP: Special Considerations

No contraindication to using Doxycycline except:

- Pregnancy, breastfeeding
- Intolerance to medication, those with severe esophageal or GI issues
- Hypersensitivity or allergies to doxycycline or other tetracyclines
- Severe liver or kidney disease



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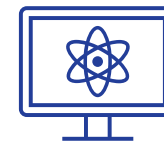
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Drug Interactions

- **Antacids and iron supplements:** Doxycycline may decrease the absorption of these medications if taken at the same time.
- **Blood thinners:** Doxycycline may increase the risk of bleeding when taken with blood thinning medications such as warfarin.
- **Retinoids:** Doxycycline may increase the risk of side effects when taken with medications such as isotretinoin.
- **Other Antibiotics:** Taking Doxycycline with other tetracycline antibiotics and penicillin antibiotics may increase the risk of side effects and decrease effectiveness.



DATA

IMPLEMENTATION

DoxyPEP: National Guidance



FEDERAL REGISTER

The Daily Journal of the United States Government



Notice

Guidelines for the Use of Doxycycline Post-Exposure Prophylaxis for Bacterial Sexually Transmitted Infection (STI) Prevention; Request for Comment and Informational Presentation

A Notice by the Centers for Disease Control and Prevention on 10/02/2023

This document has a comment period that ends in 45 days. (11/16/2023)

[SUBMIT A FORMAL COMMENT](#)

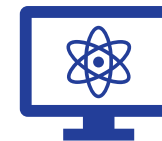
Guidelines for the Use of Doxycycline Post Exposure Prophylaxis for Bacterial Sexually Transmitted Infection Prevention

Laura Hinkle Bachmann, MD, MPH
Chief Medical Officer
Division of STD Prevention
Centers for Disease Control and Prevention

Centers for Disease Control and Prevention
National Center for HIV, Viral Hepatitis, STD, and TB Prevention



2023-09-19 14:05:04



DATA

IMPLEMENTATION

DoxyPEP: National Guidance

Draft Guidelines



Doxycycline 200mg taken once orally within 72 hours of oral, vaginal or anal sex

Should be considered for:

- Gay, bisexual, and other men who have sex with men
- Transgender women

With

A history of at least **one bacterial STI*** in the **last 12 months.**

**i.e. gonorrhea, chlamydia or syphilis*

Strength of recommendation and quality of evidence

AI



No recommendation can be given at this time on the use of doxycycline as PEP for :

- Cisgender women
- Cisgender heterosexual men
- Transgender men
- Other queer and nonbinary individuals

If this intervention is offered, it should be implemented with considerations for ancillary services.

Strength of recommendation and quality of evidence

Insufficient

There is insufficient evidence to assess the balance of benefits and harms of the use of doxycycline as PEP



DATA

IMPLEMENTATION

FI THE FENWAY INSTITUTE
FENWAY **FI** HEALTH



Thank You!

Special thanks to Ken Mayer, Jess Kraft, Sy Gitin,
Michael Traeger, TCA, NCSD and CDC/NACCHO

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Doxy as STI PEP Command Center

Cait Shea

Senior Manager, Clinical Programs



NCS D

National Coalition
of STD Directors

STD Engage May 2023

- Plenary session: DoxyPEP Implementation



STD RESOURCE

DOXY AS STI PEP COMMAND CENTER

Your hub for tools, templates, model policies, and an implementation toolkit to begin offering doxycycline as STI PEP to patients in your community.

DOXY AS STI PEP COMMAND CENTER

Doxy as STI PEP Marketing Tools

Download both print and digital marketing tools to share that your clinic is offering Doxycycline as STI PEP to patients.

[GET MARKETING MATERIALS | >](#)

DOXY AS STI PEP MARKETING TOOLS

STD RESOURCE

DOXY AS STI PEP TOOLS AND TEMPLATES

Use these tools and templates to implement Doxycycline as STI PEP in your community.



**DOXY
AS STI PEP
TOOLS &
TEMPLATES**

Template Guidelines for Doxycycline as STI PEP

Use the [Template Guidelines for Doxycycline as STI PEP](#) to recording guidelines for providing doxycycline as STI PEP in your clinic.

Quick Start Guide for Doxycycline as STI PEP

The [Quick Start Guide for Doxycycline as STI PEP](#) offers a checklist for considerations when developing policies and procedures.

Doxycycline as STI PEP 101

Use and modify [Doxycycline as STI PEP 101](#) to give providers, community members, and DIS a quick and informative introduction to doxycycline as STI PEP.

Doxycycline as STI PEP: An Overview for Pharmacists and Providers

[Doxycycline as STI PEP: An Overview for Pharmacists and Providers](#) offers providers and pharmacists basic, essential details on doxycycline as STI PEP.


Sample Letter on Doxycycline as STI PEP to Local Pharmacies

Use the [Sample Letter on Doxycycline as STI PEP to Local Pharmacies](#) to help local pharmacists understand the importance of doxycycline as STI PEP, dosing and fill quantities. Doxycycline as STI PEP is a new use for an existing drug and building pharmacist awareness can improve health equity by reducing patient barriers to drug access.

Doxycycline as STI PEP Medication Log

Use the [Doxycycline as STI PEP Medication Log](#) with patients to help them track their use of doxycycline and any side effects experienced.

Health Equity Considerations



DOXY AS STI PEP COMMAND CENTER

Health Equity Considerations for Doxycycline as STI PEP

Gay, bisexual, and other men who have sex with men (GBMSM) and transgender people experience higher rates of STIs than other populations, and the disparities are even larger for GBMSM and trans people of color. As an effective new prevention tool for cisgender GBMSM and transgender women, doxycycline as STI PEP has the potential to lessen health disparities. However, lessons learned from the introduction of PrEP for HIV and Jynneos as the Mpox vaccine demonstrate that an effective introduction of doxycycline as STI PEP will require careful attention to health equity.

The following are ways you can ensure your doxycycline as STI PEP program is equitable and prepared to serve your community.

Considerations: draft of CDC guidelines



Questions?



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