

Ending the STI Epidemic Through Prevention

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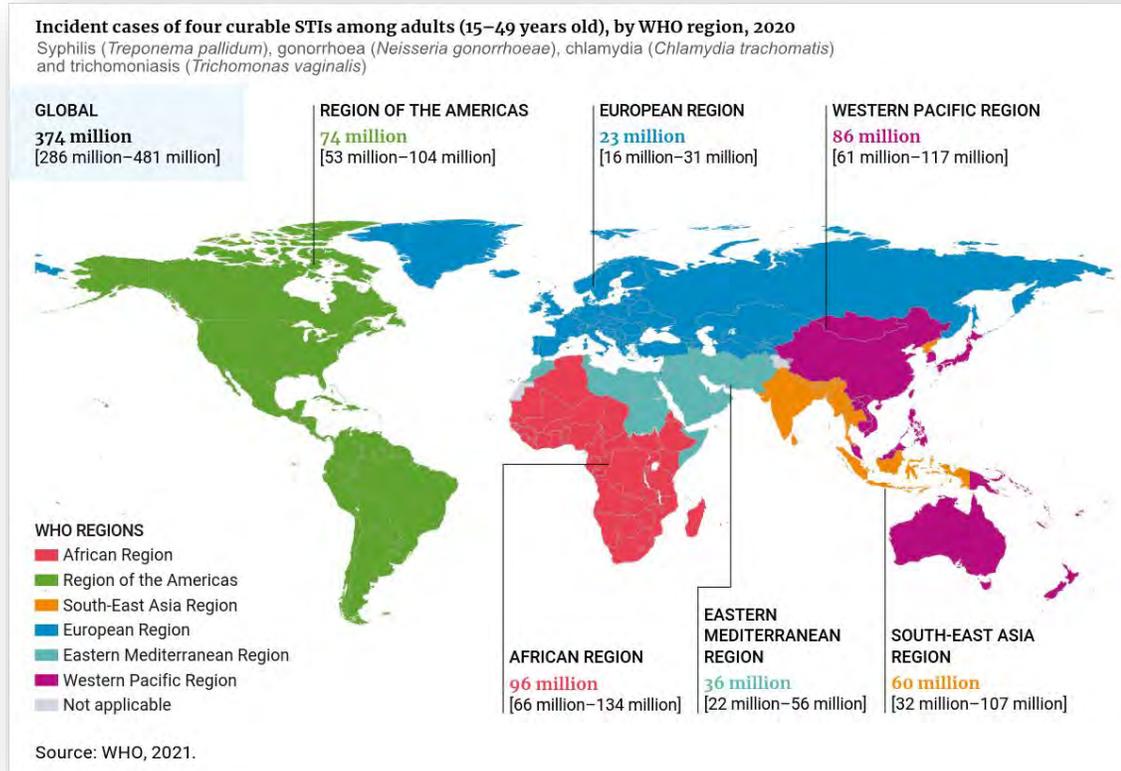
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Objectives

1. Review the state of the STI Epidemic
2. Summarize the current landscape of STI prevention options
3. Appraise new methods for STI prevention like Doxy-PEP
4. Discuss implementation of Doxy-PEP

Sexually Transmitted Infections (STIs) Are Prevalent

1 Million STIs are Acquired Every Day



The State of STIs in the U.S. in 2024

Overview

1 in 5
 People in the US have an STI
 totaling nearly **68 MILLION**
 infections in 2018

26 MILLION
 new STIs in 2018
 almost **HALF** of new STIs
 were among
 youth aged 15-24 in the US

New STIs total nearly **\$16 BILLION**
 in direct medical costs

42% increase since 2020.

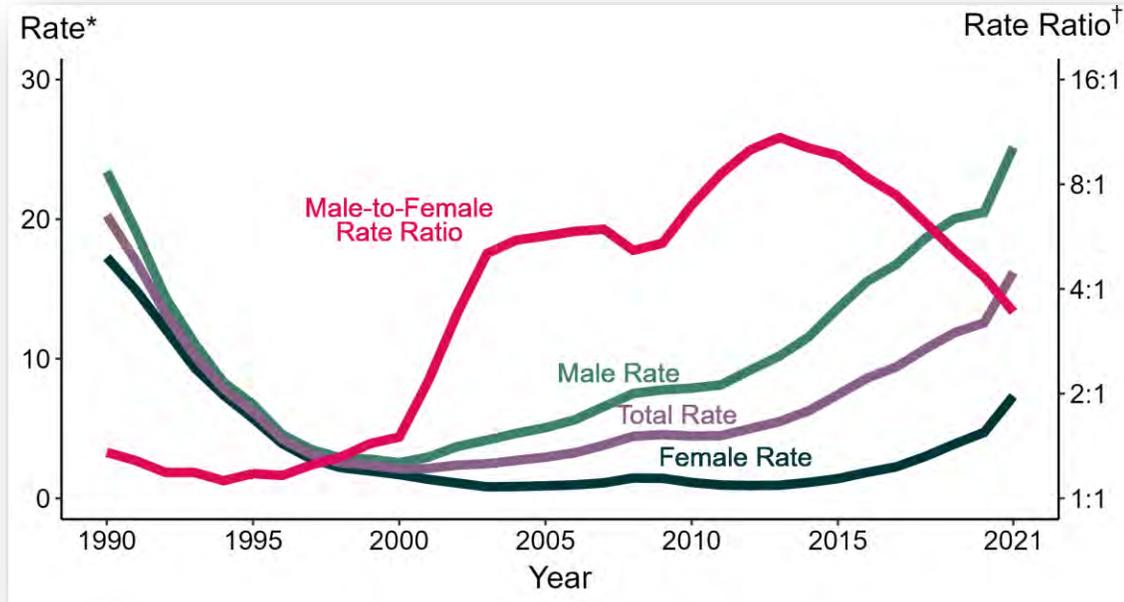
3,941 cases of **SYPHILIS**
AMONG NEWBORNS;
82% increase since 2020.



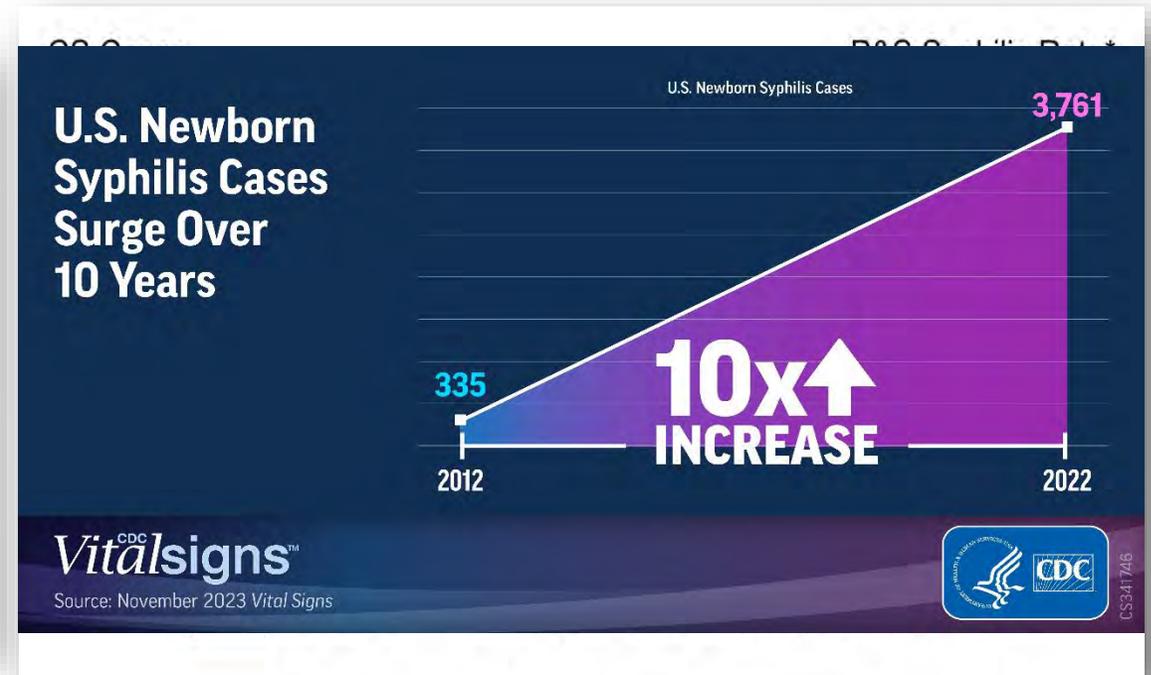
Data are provisional. Details: www.cdc.gov/sti-statistics

Why Do We Need to Prevent STIs?

Males to Female Ratio - Syphilis



Congenital Syphilis



Why Do We Need to Prevent STIs?

Rising Gonorrhea Resistance



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CLINICAL ALERT
January 19, 2023

MULTI-DRUG NON-SUSCEPTIBLE GONORRHEA IN MASSACHUSETTS

- A novel strain of multidrug-non-susceptible *Neisseria gonorrhoeae* with reduced susceptibility to ceftriaxone, cefixime, and azithromycin, and resistance to ciprofloxacin, penicillin, and tetracycline, has been identified in a Massachusetts resident. Although ceftriaxone 500 mg IM was effective at clearing infection for this case, this is the first isolate identified in the United States to demonstrate resistance or reduced susceptibility to all drugs that are recommended for treatment.
- Enhanced surveillance has identified a second isolate that, based on its genome, likely has similarly reduced susceptibility to ceftriaxone and cefixime.

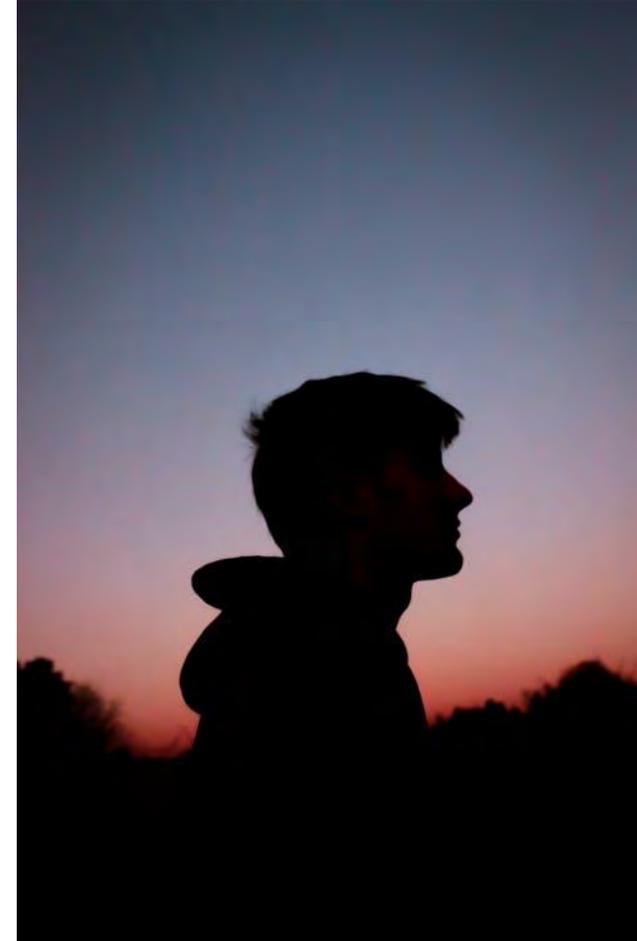
STIs Are Not Benign



- Pelvic inflammatory disease
- Chronic pelvic pain
- Infertility
- Adverse pregnancy outcomes
 - Prematurity
 - Stillbirth
- Urethral strictures
- Gastrointestinal fistulas
- Peri-rectal abscesses
- Severe complications of syphilis
 - Permanent hearing or vision impairment

Meet Marcus

- 26-year-old male, new to New York City
- Sexually active with men
 - Eight partners since his last visit, no condom usage
- Walks in to clinic due with 2 days of green penile discharge and mild rectal itching
- **Routine testing for HIV, syphilis, and three-site gonorrhea/chlamydia testing performed**
- **Treated empirically with Ceftriaxone and Doxycycline**
- **In terms of HIV/STI prevention what should we discuss with him?**



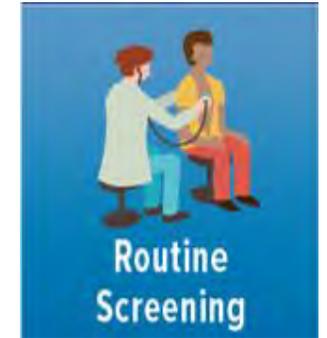
STI Prevention Landscape



• Illustrated by Barolini, Nicoletta. 2024.

CDC Routine Screening Recommendations

Population	Recommendations
Men who have sex with men	At least annually, test at each site of exposure (urethra, rectum) for sexually active MSM regardless of condom use or every 3-6 months <u>if at increased risk.</u>
Patients taking PrEP	All patients starting and taking oral PrEP should have genitourinary and extra-genital testing performed at baseline and every 3 months.
Persons living with HIV	For sexually active individuals, screen at first HIV evaluation and at least annually thereafter. More frequent screening might be appropriate depending <u>on individual risk behaviors</u> and local epidemiology
Non-pregnant Women	Test at least annually for sexually active women under 25 years of age and those aged 25 years and older <u>if at increased risk</u> Rectal chlamydial testing can be considered in females <u>based on sexual behaviors and exposure</u> through shared clinical decision making.
Men who have sex with women***	Consider screening young men in high prevalence clinical settings (adolescent and STI clinics and correctional facilities)
Pregnant Women	All pregnant women under 25 years of age and those aged 25 years and older <u>if at increased risk.</u> Retest during 3rd trimester if under 25 years of age or at risk.



Syndromic Testing, Treatment, and Presumptive Treatment

- Urethritis
- Cervicitis
- Dysuria
- Proctitis
- Pharyngitis

- Exposure

Ceftriaxone **500** mg IM x 1
for persons weighing <150kg*

*For persons weighing \geq 150kg, 1 g of IM
ceftriaxone should be administered

If chlamydia has **not** been excluded, treat for
chlamydia with:

Doxycycline 100 mg PO twice
daily x 7 days

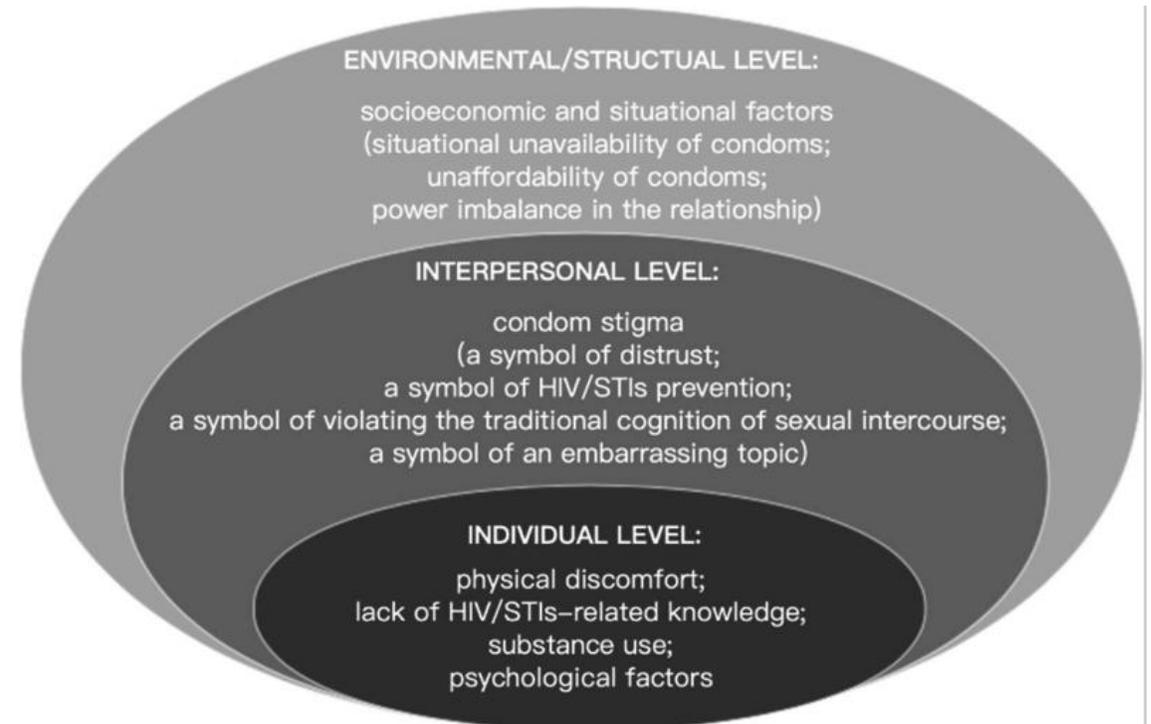
*For pregnancy, allergy, or concern for non-
adherence 1g PO Azithromycin can be used

Barrier Protection

Condoms

- When used correctly prevent multiple sexually transmitted infections
- Not as effective as HIV-PrEP
- Not used consistently for all sexual activities (i.e. oral sex)

Why Don't People Use Condoms?



Behavioral Counseling

Clinical Review & Education

JAMA | US Preventive Services Task Force | RECOMMENDATION STATEMENT

Behavioral Counseling Interventions to Prevent Sexually Transmitted Infections

US Preventive Services Task Force Recommendation Statement

The USPSTF recommends behavioral counseling for all sexually active adolescents and for adults at increased risk for sexually transmitted infections (STIs).

B



- “Behavioral counseling for persons at increased risk for STIs can reduce the likelihood of acquiring STIs (OR, 0.66 [95% CI, 0.54-0.81]) and also increase condom use or decrease the occurrence of unprotected intercourse”
- “Interventions with the largest effects for STI prevention tended to involve **more than 120 min** of total contact time and group counseling, often delivered over multiple sessions for up to 1 year”

Vaccination

Table 2 Recommended Adult Immunization Schedule by Medical Condition or Other Indication, United States, 2024

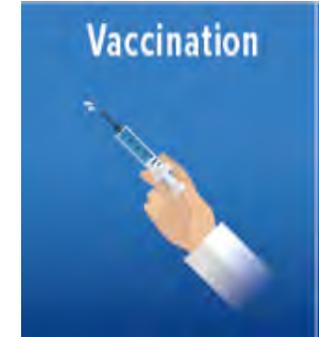
Always use this table in conjunction with Table 1 and the Notes that follow. Medical conditions or indications are often not mutually exclusive. If multiple medical conditions or indications are present, refer to guidance in all relevant columns. See Notes for medical conditions or indications not listed.

VACCINE	Pregnancy	Immunocompromised (excluding HIV infection)	HIV infection CD4 percentage and count		Men who have sex with men	Asplenia, complement deficiency	Heart or lung disease	Kidney failure, End-stage renal disease or on dialysis	Chronic liver disease; alcoholism*	Diabetes	Healthcare Personnel [†]	
			<15% or <200mm ³	≥15% and ≥200mm ³								
COVID-19		See Notes										
IPV4 or RIV4		1 dose annually										
LAIV4						1 dose annually if age 19–59 years		1 dose annually if age 19–49 years				
RSV	Seasonal administration. See Notes	See Notes					See Notes					
Tdap or Td	Tdap: 1 dose each pregnancy	1 dose Tdap, then Td or Tdap booster every 10 years										
MMR												
VAR		See Notes										
RZV		See Notes										
HPV		3 dose series if indicated										
Pneumococcal												
HepA												
Hep B	See Notes	Age ≥ 60 years										
MenACWY												
MenB												
Hib		HSCT: 3 doses [‡]					Asplenia: 1 dose					
Mpox	See Notes					See Notes	See Notes					

 Recommended for all adults who lack documentation of vaccination, OR lack evidence of immunity.
 Not recommended for all adults, but recommended for some adults based on either age OR increased risk for or severe outcomes from disease.
 Recommended based on shared clinical decision-making.
 Recommended for all adults, and additional doses may be necessary based on medical condition or other indications. See Notes.
 Precaution: Might be indicated if benefit of protection outweighs risk of adverse reaction.
 Contraindicated or not recommended. *Vaccinate after pregnancy, if indicated.
 No Guidance/Not Applicable.

Specific Recommendations

- Hepatitis A/B
- HPV
- Men ACYW
- Mpox



<https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf>

Medication Prophylaxis

Medication Prophylaxis

1. HIV post-exposure prophylaxis (PEP)
2. HIV pre-exposure prophylaxis (PrEP)
3. Doxy-PEP



STI's Are Powerful Biomarkers for HIV

The High Risk of an HIV Diagnosis Following a Diagnosis of Syphilis: A Population-level Analysis of New York City Men

Preeti Pathela,¹ Sarah L. Braunstein,² Susan Blank,^{1,3} Colin Shepard,² and Julia A. Schillinger^{1,3}

¹Bureau of Sexually Transmitted Disease Control, and ²Bureau of HIV/AIDS Prevention and Control, New York City Department of Health and Mental Hygiene, New York; ³Division of STD Prevention, Centers for Disease Control and Prevention, Atlanta, Georgia

HIV Incidence Among Men With and Those Without Sexually Transmitted Rectal Infections: Estimates From Matching Against an HIV Case Registry

Preeti Pathela,¹ Sarah L. Braunstein,² Susan Blank,^{1,3} and Julia A. Schillinger^{1,3}

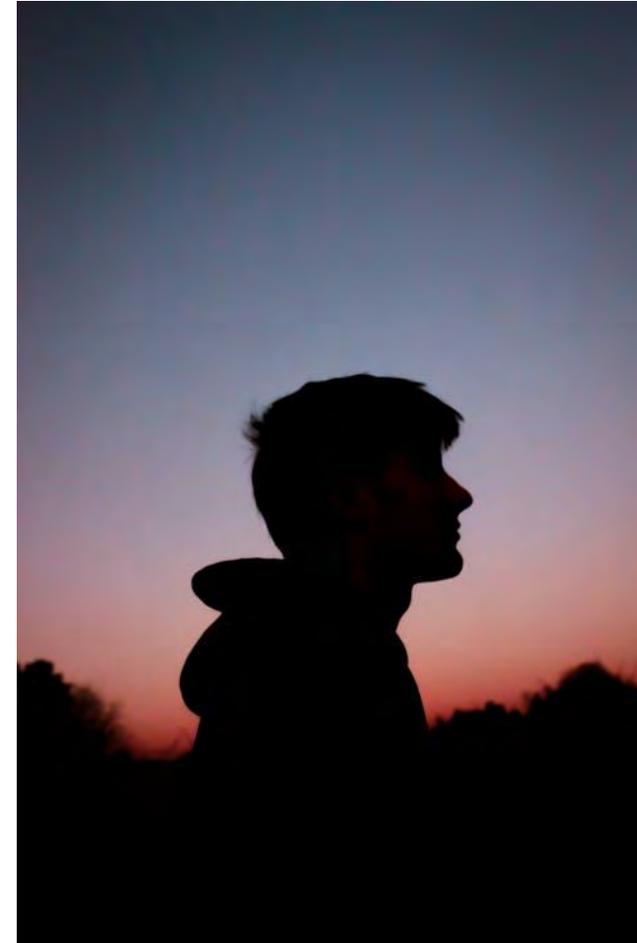
¹Bureau of Sexually Transmitted Disease Control and ²Bureau of HIV/AIDS Prevention and Control, New York City Department of Health and Mental Hygiene, New York; and ³Division of STD Prevention, Centers for Disease Control and Prevention, Atlanta, Georgia

“One in 20 MSM [with syphilis] were diagnosed with HIV within a year”

“One in 15 MSM with rectal infections was diagnosed with HIV within a year”

Meet Marcus

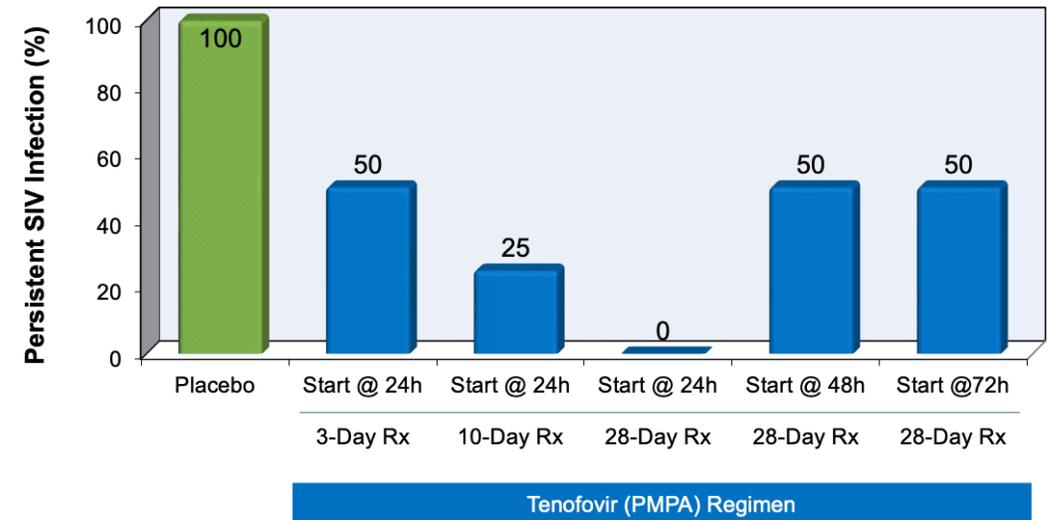
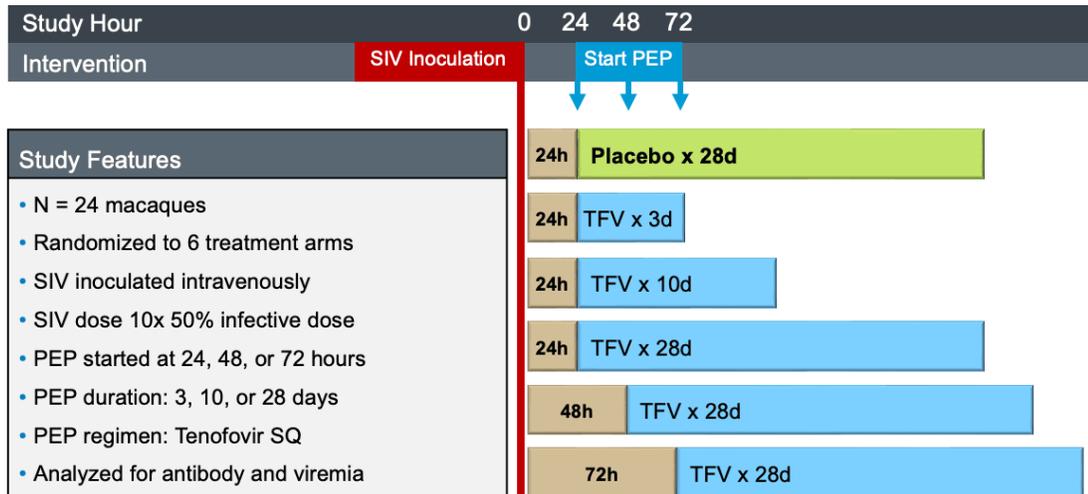
- In the course of your discussion, you learn that he engaged in condomless intercourse last evening.
- **What should you offer him now?**



PEP Is a Medical Emergency



HIV Post-Exposure Prophylaxis Time Matters

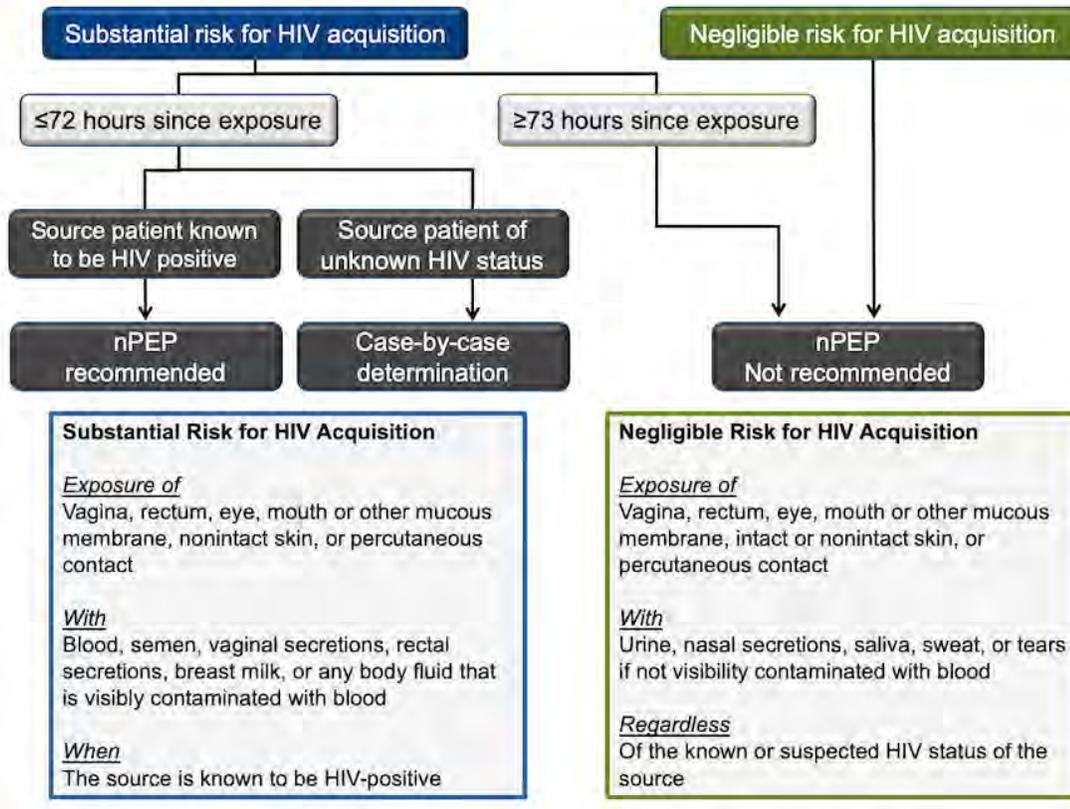


- <https://www.hiv.uw.edu/go/prevention/nonoccupational-postexposure-prophylaxis/core-concept/>
- Tsai CC, Emau P, Follis KE, et al. Effectiveness of postinoculation (R)-9-(2-phosphonylmethoxypropyl) adenine treatment for prevention of persistent simian immunodeficiency virus SIV_{mac} infection depends critically on timing of initiation and duration of treatment. *J Virol*. 1998;72:4265-73.

Evaluating Patients for HIV PrEP

Information You Need to Assess

1. Information on Exposed Persons HIV Status
2. Information Related to Source Person's HIV Status
3. Risk Related to the Exposure Type



PEP Indications By Exposure Type

Consider

- Condomless vaginal or anal intercourse during sexual abuse
- Oral sex with ejaculation or blood exposure during sexual abuse
- Injuries with exposure to blood from a source known to have HIV
- Injuries with exposure to blood from a source of unknown HIV status (including needlesticks and human bites)

Not Needed

- Kissing, spitting
- Oral-to-oral contact in the absence of mucosal damage (e.g., mouth-to-mouth resuscitation)
- Human bites not involving blood
- Exposure to needles or sharps that have not been in contact with an individual with or at risk of HIV

What Do I Need To Do For PEP?

Nonoccupational HIV PEP: Recommended Laboratory Monitoring of Source and Exposed Persons

Test	Source	Exposed			
	Baseline	Baseline	4-6 Weeks after exposure	3 Months after exposure	6 Months after exposure
		For all persons considered for or prescribed nPEP for			
HIV-1/2 Ag/Ab (or Ab testing if Ag/Ab test unavailable) ^a	✓	✓	✓		
Hepatitis B serology, including: HBsAg anti-HBs anti-HBc	✓	✓			✓ ^c
Hepatitis C antibody test	✓	✓		—	✓ ^d
		For all persons with sexual exposure			
Syphilis serology ^e	✓			—	✓
Gonorrhea ^f			✓ ^e	—	—
Chlamydia ^f			✓ ^e	—	—
Pregnancy ^h			✓	—	—
		For persons prescribed: Tenofovir DF-emtricitabine + raltegravir Tenofovir DF-emtricitabine + dolutegravir			
		✓	✓	—	—
		✓	✓	—	—
		For all persons with HIV confirmed at any visit			
HIV RNA level	✓			✓	
HIV genotypic drug resistance test	✓			✓	

Assessment of exposure, HIV and other baseline testing, and other related activities can proceed after the first dose of PEP is administered.

NEW HIV PEP Guidelines

Post-Exposure Prophylaxis (PEP) to Prevent HIV Infection

Date of current publication: October 3, 2024

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Committee: [Medical Care Criteria Committee](#)

Date of original publication: June 25, 2020

Contents

Purpose of This Guideline	3
Risk of Infection Following an Exposure to HIV	4
Occupational Exposure Risk	4
Non-Occupational Exposure Risk	5
Sexual Assault Exposure Risk	7
Exposure Risk in Children	7
Rationale for PEP and Evidence of PEP Effectiveness	8
First Dose of PEP and Management of the Exposure Site	10
Exposure to HIV Is An Emergency	11
Managing the Exposure Site	13
When to Consult an Expert Regarding the First Dose of PEP	13
Evaluating Exposure Risk	13
Evaluating Occupational Exposure Risk	14
Evaluating Non-Occupational Exposure Risk	15
Evaluating Sexual Assault Exposure Risk	19
Considerations for Sexual Assault in Children	22
Source HIV Status and Management	23

Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV — CDC Recommendations, United States, 2025

Group	Preferred/Alternative	Regimen* ^{1,5}
Adults and adolescents aged ≥12 yrs	Preferred	Integrase strand transfer inhibitors PLUS two nucleoside reverse transcriptase inhibitors <ul style="list-style-type: none"> Bictegravir/emtricitabine/tenofovir alafenamide, OR Dolutegravir PLUS (tenofovir alafenamide OR tenofovir disoproxil fumarate) PLUS (emtricitabine OR lamivudine)
	Alternative	Boosted protease inhibitor PLUS two nucleoside reverse transcriptase inhibitors <ul style="list-style-type: none"> Darunavir and cobicistat OR darunavir and ritonavir PLUS (tenofovir alafenamide OR tenofovir disoproxil fumarate) PLUS (emtricitabine OR lamivudine)
Pregnant women	Preferred	Integrase strand transfer inhibitors PLUS two nucleoside reverse transcriptase inhibitors <ul style="list-style-type: none"> Bictegravir/emtricitabine/tenofovir alafenamide, OR Dolutegravir PLUS (tenofovir alafenamide OR tenofovir disoproxil fumarate) PLUS (emtricitabine OR lamivudine)
	Alternative	Integrase strand transfer inhibitors PLUS two nucleoside reverse transcriptase inhibitors Boosted protease inhibitor PLUS two nucleoside reverse transcriptase inhibitors <ul style="list-style-type: none"> Darunavir and ritonavir (twice daily) PLUS (tenofovir alafenamide OR tenofovir disoproxil fumarate) PLUS (emtricitabine OR lamivudine)
Children aged ≥2 yrs to 12 yrs	Preferred	Integrase strand transfer inhibitors PLUS two nucleoside reverse transcriptase inhibitors <ul style="list-style-type: none"> Bictegravir/emtricitabine/tenofovir alafenamide (≥14 kg),⁶ OR Dolutegravir PLUS (tenofovir alafenamide OR tenofovir disoproxil fumarate) PLUS (emtricitabine OR lamivudine)

Selecting and Initiating a 28-Day Course of PEP

RECOMMENDATIONS

Preferred Regimens

- Clinicians should administer a preferred or alternative PEP regimen (the following recommended regimens also have activity in the rare possibility of an exposure to known HIV-2 or a source patient at risk of HIV-2 infection): (A2)
 - Preferred single-tablet regimen: BIC/TAF/FTC by mouth once daily (preferred because of the lower discontinuation rates and minimal adverse effects).
 - Preferred multi-tablet regimen [a,b]: TDF/FTC plus either RAL or DTG; 3TC may be substituted for FTC in either regimen.
 - For alternative regimens, see [Table 3: Alternative PEP Regimens for Patients Who Weigh ≥40 kg](#).

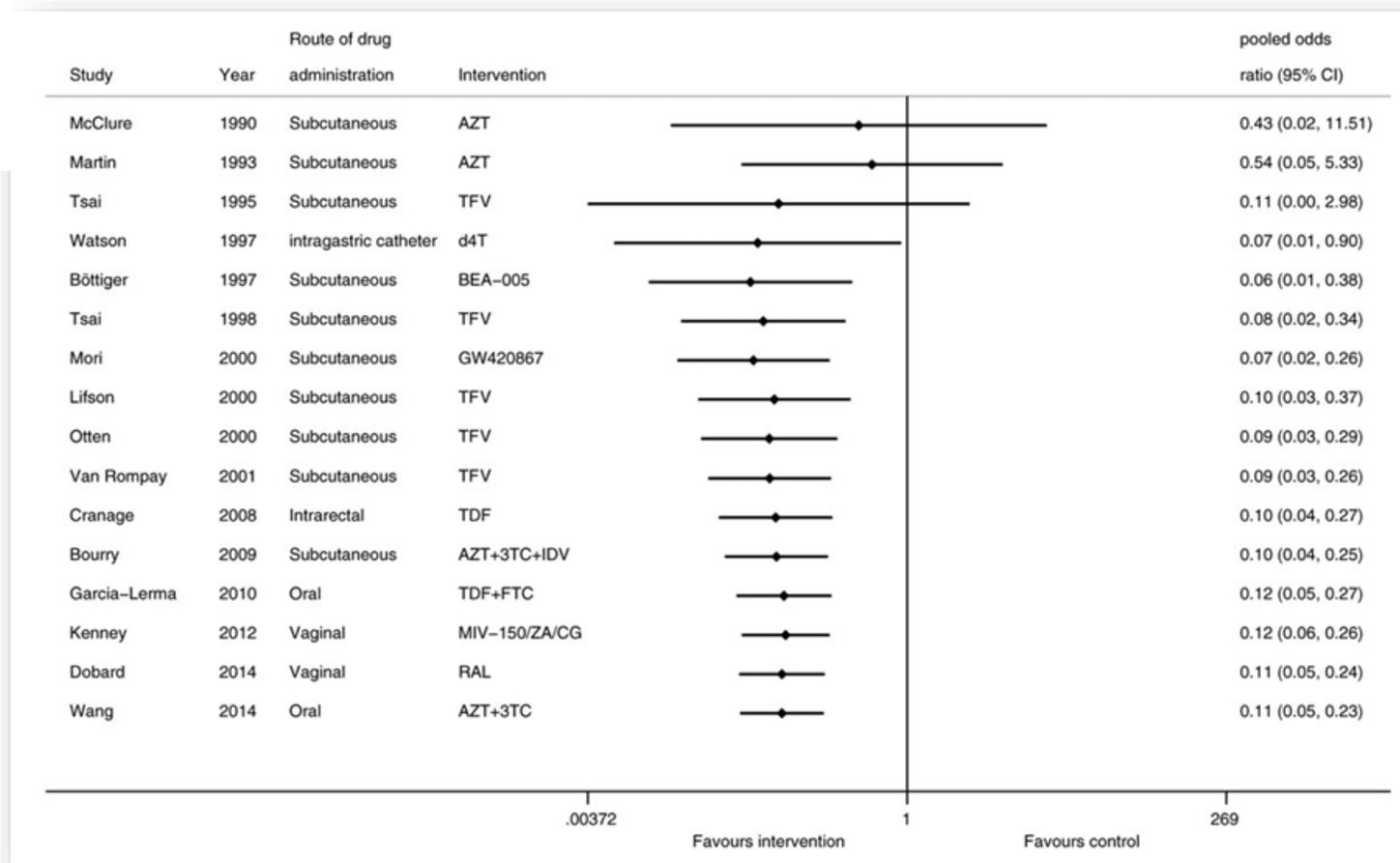
- Cowan E, Kerr CA, Fernandez A, et al. *PEP to Prevent HIV Infection*. Baltimore (MD): Johns Hopkins University; October 2024.
- https://www.cdc.gov/mmwr/volumes/74/rr/rr7401a1.htm?s_cid=rr7401a1_w#B1_down

Efficacy of HIV PEP

Efficacy of HIV Postexposure Prophylaxis: Systematic Review and Meta-analysis of Nonhuman Primate Studies

Cadi Irvine,¹ Kieren J. Egan,² Zara Shubber,³ Koen K. A. Van Rompay,⁴ Rachel L. Beanland,¹ and Nathan Ford¹

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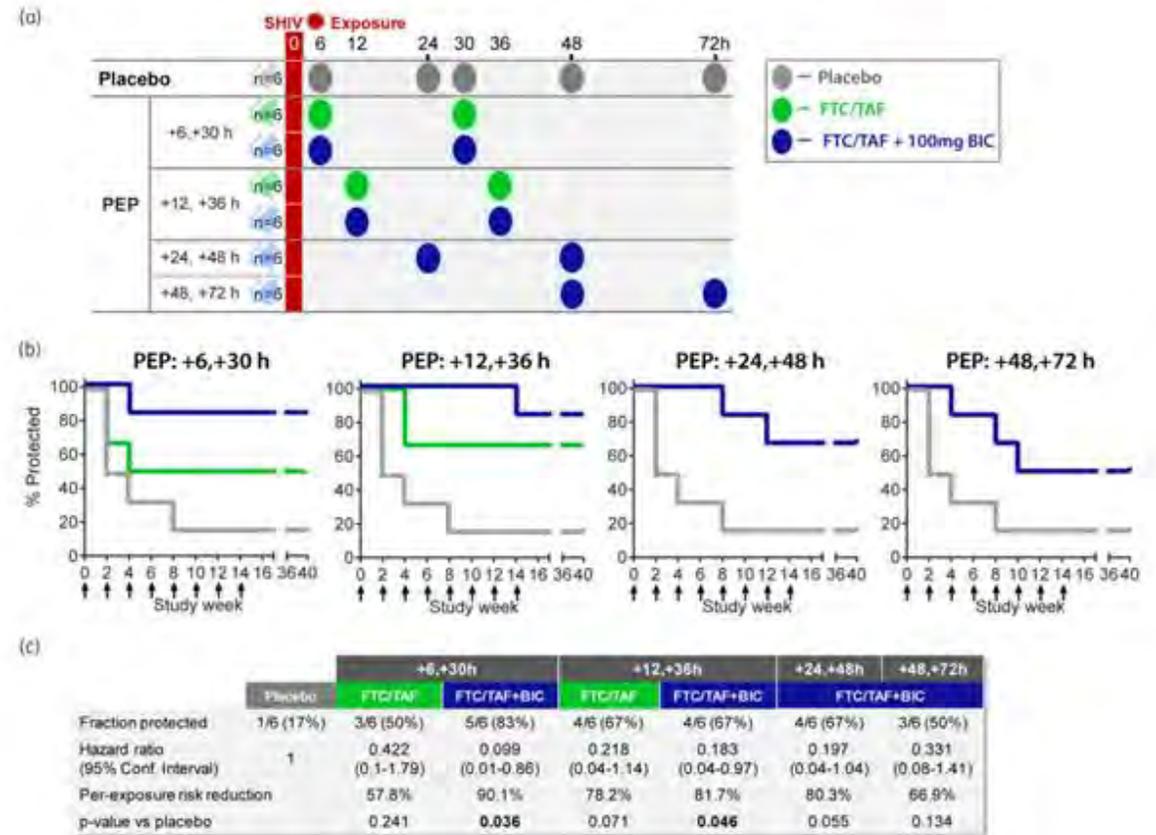


Efficacy of HIV PEP With BIC/FTC/TAF

Two-dose emtricitabine/tenofovir alafenamide plus bictegravir prophylaxis protects macaques against SHIV infection

Elena Bekerman^{1*}, Stephanie Cox¹, Darius Babusis¹, Federico Campigotto¹, Moupali Das¹, Dan H. Barouch², Tomas Cihlar¹ and Christian Callebaut¹

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Real-World Data on BIC/FTC/TAF for HIV-PEP

PREVENTION RESEARCH

Safety and Tolerability of Once Daily Coformulated Bictegravir, Emtricitabine, and Tenofovir Alafenamide for Postexposure Prophylaxis After Sexual Exposure

Kenneth H. Mayer, MD,^{a,b,c} Marcy Gelman, NP,^a Johnathon Holmes, NP,^a Jessica Kraft, NP,^a
Kathleen Melbourne, PharmD,^d and Matthew J. Mimiaga, ScD, MPH^{a,e}

TABLE 1. Demographic and Behavioral Risk Profile of Participants Who Used BIC/FTC/TAF for Postexposure Prophylaxis (N = 52)

	Mean (Range)
Age, yrs	37.2 (21–71)
Race	% (n)
White	76.9 (40)
Black/African American	5.8 (3)
Asian/Pacific Islander	5.8 (3)
Multiracial	11.5 (6)
Ethnicity	% (n)
Lantinx/Hispanic	9.6 (5)
Sexual orientation/gender identity	% (n)
Gay/cisgender man	67.3 (35)
Bisexual/cisgender man	11.5 (6)
Heterosexual/cisgender man	7.7 (4)
Heterosexual/cisgender woman	3.8 (2)
“Heteroflexible”/cisgender man	1.9 (1)
Pansexual/cisgender man	1.9 (1)
Queer/transgender man	1.9 (1)
Declined/cisgender man	1.9 (1)
Sexual behavior (yes/no)	% yes (n)
Receptive anal sex	51.9 (27)
Insertive anal sex	42.3 (22)
Receptive vaginal sex	5.8 (3)
Insertive vaginal sex	5.8 (3)
Receptive or insertive oral sex	57.7 (30)
Condomless anal or vaginal sex with a known HIV-Positive partner	15.4 (8)

- Mayer KH, Gelman M, Holmes J, Kraft J, Melbourne K, Mimiaga MJ. Safety and Tolerability of Once Daily Coformulated Bictegravir, Emtricitabine, and Tenofovir Alafenamide for Postexposure Prophylaxis After Sexual Exposure. *J Acquir Immune Defic Syndr*. 2022;90(1):27-32. doi:10.1097/QAI.0000000000002912



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BIC/FTC/TAF Had Lower Rates of Side Effects

TABLE 2. Commonly Reported Adverse Events Among BIC/FTC/TAF PEP Users Compared With Those Using Other PEP Regimens, Fenway Health, Boston, 2000–2020

	AZT/3TC/PI (N = 119) %	TDF/FTC/RAL (N = 100) %	EVG/COB/FTC/TDF (N = 100) %	BIC/FTC/TAF (N = 52) %
	Dates Recruited			
	January 2000–May 2004	March 2008–March 2010	May 2013–November 2015	August 2018–March 2020
Diarrhea/loose stool	58.8*	21.0†	38.0*	7.7
Fatigue	48.5*	14.0	28.0‡	9.6
Nausea/vomiting	58.8*	27.0	28.0	15.4
Headache	11.8†	15.0‡	14.0‡	1.9
Dizziness/lightheadedness	8.4†	10.0‡	6.0	0.0
Myalgia/arthralgia	10.9†	8.0	2.0	1.9

- Mayer KH, Gelman M, Holmes J, Kraft J, Melbourne K, Mimiaga MJ. Safety and Tolerability of Once Daily Coformulated Bicitegravir, Emtricitabine, and Tenofovir Alafenamide for Postexposure Prophylaxis After Sexual Exposure. *J Acquir Immune Defic Syndr*. 2022;90(1):27-32. doi:10.1097/QAI.0000000000002912

BIC/FTC/TAF Had Higher Completion Rates

TABLE 3. Regimen Completion Rates Among TAF/FTC/BIC Users Compared With Those Using Other Postexposure Prophylaxis Regimens, Fenway Health, Boston, 2000–2020

	AZT/3TC/PI	TDF/FTC/RAL	EVG/COB/FTC/TDF	BIC/FTC/TAF
	(N = 119)	(N = 100)	(N = 100)	(N = 52)
	%	%	%	%
Dates Recruited				
	January 2000–May 2004	March 2008–March 2010	May 2013–November 2015	August 2018–March 2020
Completed as prescribed	38.8*	57.0†	71.0‡	90.4
Stopped or modified	14.0†	28.0*	15.0†	0
Lost to follow-up	47.3*	15.0	14.0	9.6

- Mayer KH, Gelman M, Holmes J, Kraft J, Melbourne K, Mimiaga MJ. Safety and Tolerability of Once Daily Coformulated Bictegravir, Emtricitabine, and Tenofovir Alafenamide for Postexposure Prophylaxis After Sexual Exposure. *J Acquir Immune Defic Syndr*. 2022;90(1):27-32. doi:10.1097/QAI.0000000000002912

Low Side Effects and High Completion Rates Seen

OPTIONS LAB **BIC/FTC/TAF as HIV PEP was well-tolerated with high adherence and no seroconversions** 1134

Darrell H. S. Tan^{1,2,3}, Reva Persaud¹, Atia Qamar¹, Isaac Bogoch^{4,5}, Arlene Chan⁶, Allison Chris⁷, Karla Fisher⁸, Richard T. Lester⁹, John Maxwell¹⁰, James Murray¹¹, Hong Qian¹¹, Hubert Wong¹¹

1. MAP Centre for Urban Health Solutions, St. Michael's Hospital, Toronto, Canada; 2. Division of Infectious Diseases, St. Michael's Hospital, Toronto, Canada; 3. Department of Medicine, University of Toronto, Toronto, Canada; 4. Scarborough Health Network, Toronto, Canada; 5. Division of Infectious Diseases, Toronto General Hospital; 6. Women's College Hospital, Toronto, Canada; 7. Toronto Public Health, Toronto, Canada; 8. University of British Columbia, Vancouver, Canada; 9. AIDS Committee of Toronto (ACT), Toronto, Canada; 10. AIDS Bureau, Ontario Ministry of Health and Long-Term Care, Toronto, Canada; 11. CHR Canadian HIV Trials Network, Vancouver, Canada

BACKGROUND

- Integrase strand transfer inhibitors-based regimens have become standard of care for HIV post-exposure prophylaxis (PEP)
- No single tablet regimens recommended in current Canadian guidelines

OBJECTIVES

- Describe 1. tolerability and 2. adherence to bicitegravir, emtricitabine and tenofovir alafenamide (BIC/FTC/TAF) as HIV PEP in an ongoing clinical trial of text message support vs standard of care

METHODS

- Design:** Descriptive analysis of participants enrolled in an RCT of a text-messaging intervention (Weltel) for supporting PEP follow-up
- Eligibility:**
 - HIV-negative adults aged ≥18 years
 - Initiated PEP within past 6 days for sexual exposure
 - Able/willing to receive texts via mobile phone
 - Able to communicate in English
- Recruitment (Figure 1):**
 - Information cards given to patients receiving PEP in emergency departments
- Study procedures (Figure 2):**
 - At enrollment, participants switched to BIC/FTC/TAF to complete 28 days
 - Adherence** (#days of PEP taken) assessed via telephone call at week 4
 - HIV status** assessed at baseline, week 6, week 12

RESULTS

- Of 120 enrolled participants, 1 was HIV seropositive at baseline leaving n=119 included in the analysis.

Table 1: Participant characteristics (n=119)

Characteristic	n (%)	n (%)	
Age	29.3 (25.8, 34.4)	No partners in 72h prior to PEP	1 (0.8)
Sexual orientation and gender		Type of zoonoemesis exposure [†]	
Men who have sex with men	97 (81)	Anal exposure	40 (34)
Heterosexual man	20 (17)	Anal receptive or ejaculation	36 (30)
Heterosexual woman	2 (2)	Anal receptive without ejaculation	21 (18)
Rheological identity		Vaginal exposure	15 (13)
White	14 (12)	Vaginal receptive or ejaculation	8 (7)
Black	8 (7)	Vaginal receptive without ejaculation	1 (1)
Asian	34 (29)	Partner's reported HIV status	
Latin American	33 (28)	Positive	12 (10)
Identity other than those of above	9 (8)	Negative or unknown	107 (90)
Consolidation in 10% of sample	9 (8)	Previously prescribed PEP regimen	
ABO	8 (7)	DTG + TDF/FTC	106 (89)
Rhesus/D Rh factor	7 (6)	BIC + TDF/FTC	2 (2)
No. times previously used PEP		BIC/FTC/TAF	15 (13)
0	95 (79)	Days off PEP before BIC/FTC/TAF	2 (1.7)
1	24 (20)	Prior knowledge of PEP	
≥ 2	8 (7)	Unknown	100 (82)
No. with prior diagnosis of STI		Always but never used PEP	59 (50)
Gonorrhoea	21 (18)	Previously used PEP	12 (10)
Chlamydia	24 (20)	Never	54 (45)
Lymphegnoadenopathy	2 (2)	Willing to be HIV tested	86 (72)
Syphilis	25 (21)	Willing to be HIV tested	86 (72)
Genital warts	7 (6)	Part 6-24 months	2 (2)
Genital herpes	8 (7)	Never but willing not provided	67 (56)

[†] Values represent median (Ist quartile, 9th quartile) or frequency (percentage). Values may not all sum to 100 due to missing values.
[‡] Highest risk type of sexual exposure reported.
 Range: 1-6.

Figure 1: Recruitment card

Figure 2: Study design

Table 2: Adverse events occurring in >3% of participants

Adverse event	Number (n) (% of participants)	Number (n) (% of participants)	n not given, or were already taking by study drug (n) (% of participants)
Headache	8 (8%)	8 (8%)	8 (8%)
Dizziness	5 (5%)	4 (4%)	5 (5%)
Nausea	2 (2%)	2 (2%)	2 (2%)
Diarrhea	5 (5%)	5 (5%)	5 (5%)
Stomach pain	2 (2%)	2 (2%)	2 (2%)
Insomnia	1 (1%)	1 (1%)	1 (1%)
Sleep disturbance	4 (4%)	4 (4%)	4 (4%)

Figure 3: Total number of days of PEP taken

RESULTS

- Tolerability:** Only 10% experienced adverse events of grade ≥2 severity
- Adherence:** 90/102 or 88% of participants with available data reported completing ≥28 days of PEP

Table 3: Limitations

- No HIV seroconversions among n=66 (55%) of participants tested at week 12
- N=28 (23%) of participants initiated on PrEP by final visit
- N=18 (13%) linked to other primary care/mental health providers

DISCUSSION

- Limitations:**
 - Biomarkers of PEP adherence not done
 - Some AEs may be related to prior PEP drugs since participants switched to BIC/FTC/TAF after a median of 2 (1,3) days of another regimen
- Findings similar to other reports of BIC/FTC/TAF PEP (n=164 total)
- JAIDS 2022;90:27-32 and Chinese Med J 2022;135(22)
- Conclusions:**
 - BIC/FTC/TAF PEP was safe, well-tolerated and associated with high adherence and no HIV seroconversions.
 - BIC/FTC/TAF is an appropriate single tablet INSTI-based HIV PEP regimen

CONSPONSORSHIP: darrelltan@gmail.com
ACKNOWLEDGEMENTS:

- We gratefully acknowledge grant funding from the Canadian Institutes of Health Research and the CHR Canadian HIV Trials Network, and in-kind support from Gilead Sciences Inc.
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Original Article

Chinese Medical Journal

An open-label evaluation of safety and tolerability of coformulated bicitegravir/emtricitabine/tenofovir alafenamide for post-exposure prophylaxis following potential exposure to human immunodeficiency virus-1

An Liu¹, Ruolei Xin², Hongwei Zhang¹, Lili Dai¹, Ruojun (Esther) Wu³, Xi Wang¹, Aixin Li¹, Wei Hua¹, Jianwei Li¹, Ying Shao¹, Yue Gao¹, Zhangli Wang¹, Jiangzhu Ye¹, Gulimila A bu dou re xi ti⁴, Zaicun Li¹, Lijun Sun¹

¹Clinic of Center for Infection, Beijing Youan Hospital, Capital Medical University, Beijing 100069, China;

²Institute of STD/AIDS Prevention and Control, Beijing Center for Disease Prevention and Control, Beijing 100013, China;

³Department of Chemistry, Colgate University, Hamilton NY, USA;

⁴Care Center, The Eighth Affiliated Hospital of Xinjiang Medical University, Urumchi, Xinjiang 830054, China.

Consider BIC/TAF/FTC?

- Efficacy
 - Animal studies demonstrated up to 91% protection with early initiation.
 - Animal studies suggest improved efficacy with late initiation
 - No HIV seroconversions reported in multiple human studies.
- Tolerability
 - Significantly fewer side effects (e.g., diarrhea, fatigue) compared to older PEP regimens.
 - Well-tolerated in both real-world and clinical trial settings.
- Completion Rates:
 - Over 90% regimen completion in multiple studies.
 - Single-tablet regimen enhances adherence.
- Accessibility
 - On most formularies
 - Single manufacturer for patient assistance programs
- Recommended in the NYS AIDS Institute Guidelines and **gaining traction in other jurisdictions**
- Consistent findings across animal, observational, and randomized studies highlight its safety and effectiveness.

Medication Prophylaxis

Medication Prophylaxis

1. HIV post-exposure prophylaxis (PEP)
2. **HIV pre-exposure prophylaxis (PrEP)**
3. Doxy-PEP



Updated PrEP Recommendations

US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES – 2021 UPDATE

A CLINICAL PRACTICE GUIDELINE

- Discuss PrEP with **more** people
- Do **more** HIV testing
- Expand PrEP options to appeal to **more** people
 - Tailored recommendations for initiation and follow-up care

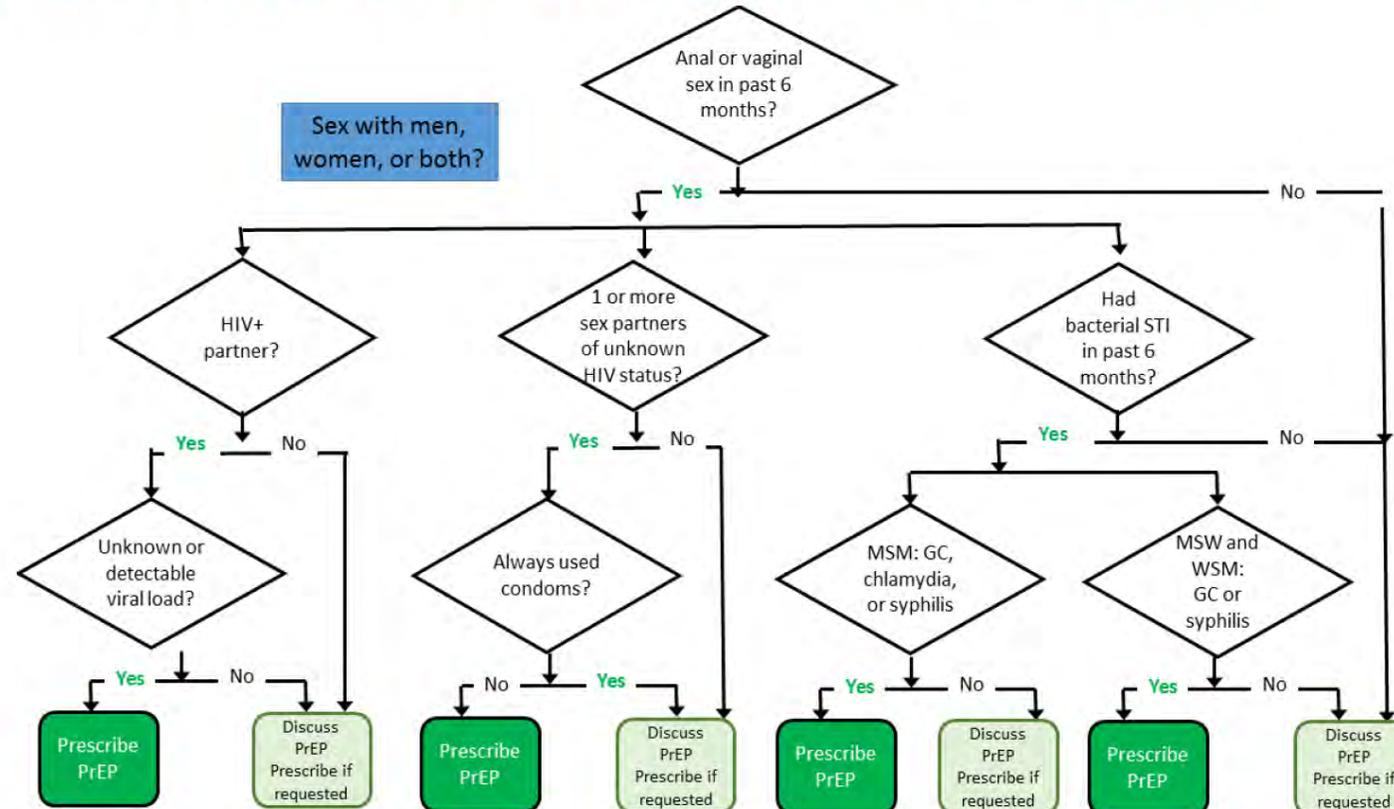
Updated Recommendations



- Inform **all** sexually active adults and adolescents about PrEP
 - Risk-based screening tools and algorithms don't work and stigmatize patients
 - Universal HIV/STI screening and PrEP education is more beneficial and cost effective than risk-based screening

Updated Recommendations

PrEP Indications for Sexually Active Persons



The Era of PrEP Choice

Option	Type / Brand	How to Use	Effectiveness	Common Side Effects	Monitoring	Approx. Cost*
Daily Oral (TDF/FTC)	Truvada	1 pill daily	99%	Nausea, diarrhea, fatigue	Labs every 3–6 mo	\$30/mo
Daily Oral (F/TAF)	Descovy	1 pill daily	99%	Nausea, fatigue, weight gain	Labs every 3–6 mo	\$2,200/mo

TDF vs TAF

1. There is a robust evidence base for the use of TDF/FTC as PrEP
2. TAF/FTC has not been shown to be more effective than TDF/FTC
3. TDF/FTC is extremely safe
4. Continuing to prescribe TDF/FTC may allow us to expand PrEP use

Tenofovir Alafenamide for HIV Preexposure Prophylaxis — What Can We DISCOVER About Its True Value?

Douglas S. Krakower, MD^{1,2,3}, Demetre C. Daskalakis, MD⁴, Judith Feinberg, MD⁵, Julia L. Marcus, PhD^{2,3}

¹Beth Israel Deaconess Medical Center, Boston, MA, USA

²Harvard Medical School and Harvard Pilgrim Health Care Institute, Boston, MA, USA

³The Fenway Institute, Boston, MA, USA

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⁵West Virginia University, Morgantown, WV, USA

On-Demand PrEP Works

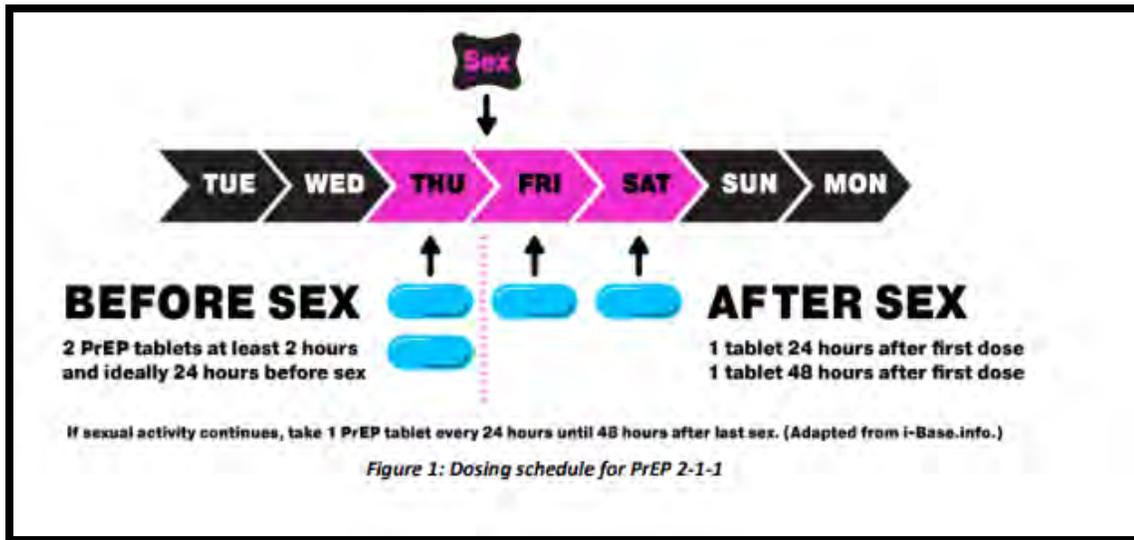
ORIGINAL ARTICLE

On-Demand Preexposure Prophylaxis in Men at High Risk for HIV-1 Infection

J.-M. Molina, C. Capitant, B. Spire, G. Pialoux, L. Cotte, I. Charreau, C. Tremblay, J.-M. Le Gall, E. Cua, A. Pasquet, F. Raffi, C. Pintado, C. Chidiac, J. Chas, P. Charbonneau, C. Delaugerre, M. Suzan-Monti, B. Loze, J. Fonsart, G. Peytavin, A. Cheret, J. Timsit, G. Girard, N. Lorente, M. Préau, J.F. Rooney, M.A. Wainberg, D. Thompson, W. Rozenbaum, V. Doré, L. Marchand, M.-C. Simon, N. Etien, J.-P. Aboulker, L. Meyer, and J.-F. Delfraissy, for the ANRS IPERGAY Study Group*

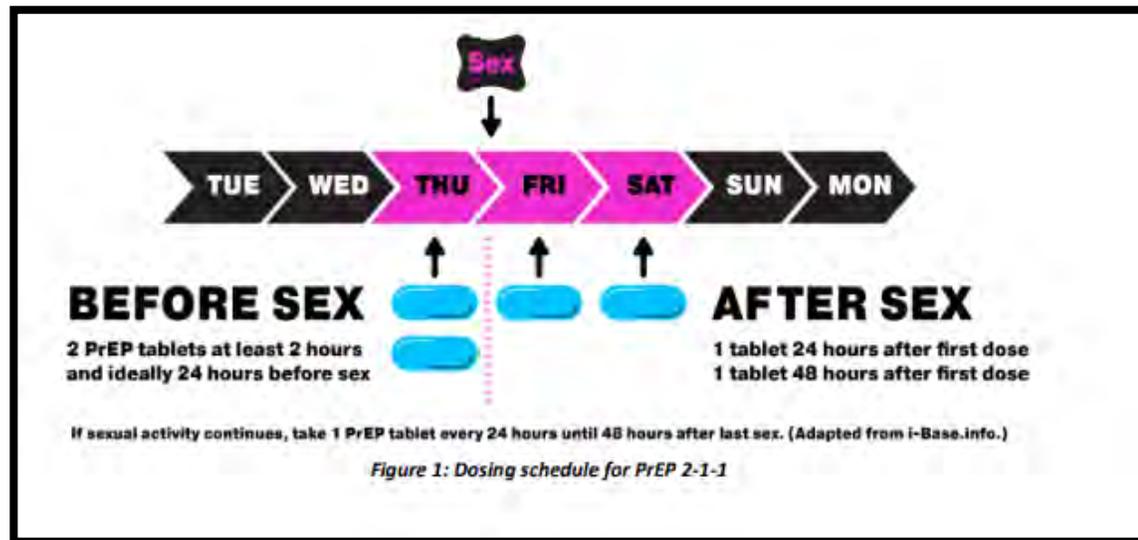
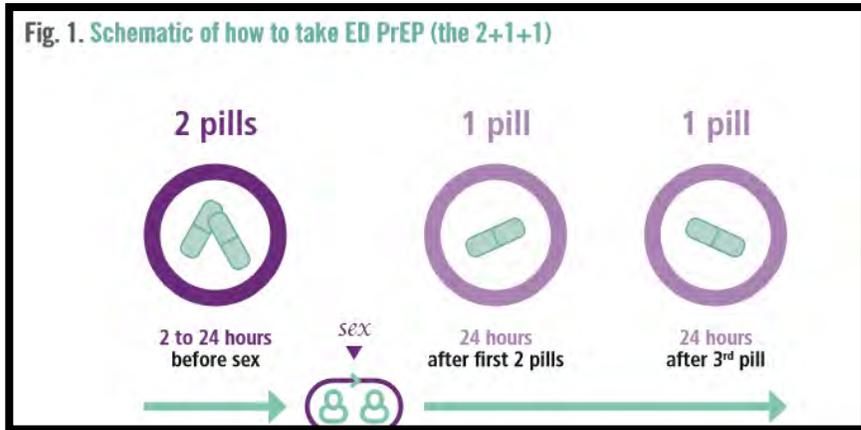
- 414 patients randomized to placebo vs on-demand PrEP
- **86% relative reduction in HIV incidence compared with placebo**
- **The use of TDF-FTC before and after sexual activity provided protection against HIV-1 infection in men who have sex with men.**

On-Demand PrEP



1. First dose: 2 tablets 2-24 hours (ideally 24 hours) before sex
2. Second dose: 1 tablet 24 hours after the first dose
3. Third dose: 1 tablet 48 hours after the first dose
4. If you have sex later than planned or multiple times:
 1. Keep taking additional tablets until you have taken two tablets in the 48 hours (once every 24 hours) after your last sexual encounter
5. If you have sex more than twice a week, take daily PrEP instead

On-Demand (Great For Starts and Stops)



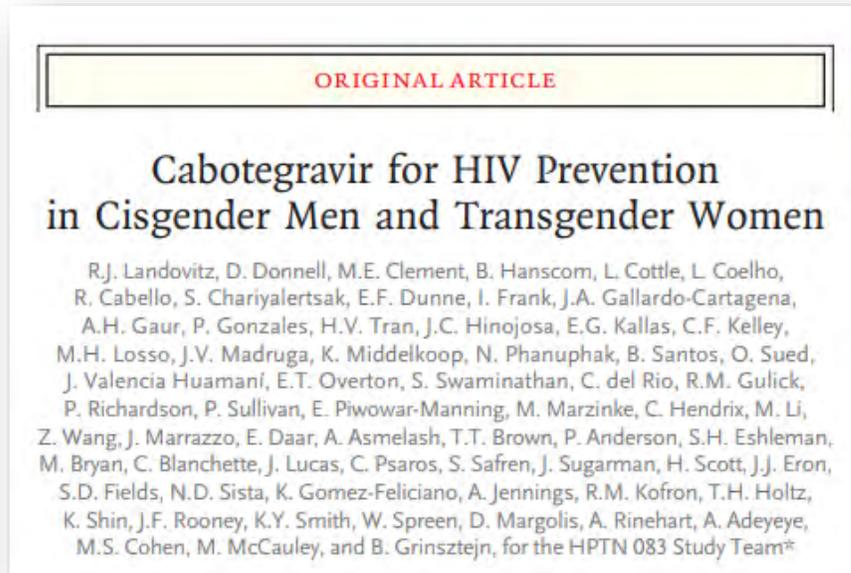
- Only for men who have sex with men
 - Limited data for cisgender women, transgender women, and transgender men having vaginal/frontal sex
- Infrequent sex
- Able to plan for sex at least 2 hours in advance
- Contraindicated in Hepatitis B infection

The Era of PrEP Choice

Option	Type / Brand	How to Use	Effectiveness	Common Side Effects	Monitoring	Approx. Cost*
Daily Oral (TDF/FTC)	Truvada	1 pill daily	99%	Nausea, diarrhea, fatigue	Labs every 3–6 mo	\$30/mo
Daily Oral (F/TAF)	Descovy	1 pill daily	99%	Nausea, fatigue, weight gain	Labs every 3–6 mo	\$2,200/mo
On-Demand (TDF/FTC)	“2-1-1” dosing	2 pills ≥2h before sex, 1 after 24h, 1 after 48h	86%	GI upset	Labs every 3–6 mo	~\$30/mo (depends on use)

Injectable PrEP - Cabotegravir

HPTN083



- CAB-LA was **superior** to daily oral TDF–FTC in preventing HIV infection among MSM and transgender women

HPTN084



- **Superiority** of Injectable Cabotegravir to Oral TDF/FTC for the Prevention of HIV in Cisgender Women in Sub-Saharan Africa

Injectable PrEP - Lenacapavir

Purpose - 1

ORIGINAL ARTICLE

Twice-Yearly Lenacapavir or Daily F/TAF for HIV Prevention in Cisgender Women

Authors: Linda-Gail Bekker, M.B., Ch.B., Ph.D., Moupali Das, M.D., M.P.H., Quarraisha Abdool Karim, Ph.D., Khatija Ahmed, M.B., B.Ch., Joanne Bating, M.B., Ch.B., D.F.S.R.H., D.R.C.O.G., Dip. HIV Man., William Brumskine, M.B., Ch.B., Dip. HIV Man., Katherine Gill, M.B., Ch.B., M.P.H., for the PURPOSE1 Study Team* [Author Info & Affiliations](#)

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- **No participants** receiving twice-yearly lenacapavir acquired HIV infection.

Purpose - 2

ORIGINAL ARTICLE

Twice-Yearly Lenacapavir for HIV Prevention in Men and Gender-Diverse Persons

Authors: Colleen F. Kelley, M.D., M.P.H., Maribel Acevedo-Quiñones, M.D., Allison L. Agwu, M.D., Anchalee Avihingsanon, M.D., Ph.D., Paul Benson, D.O., Jill Blumenthal, M.D., Cynthia Brinson, M.D., for the PURPOSE 2 Study Team* [Author Info & Affiliations](#)

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- The HIV incidence with twice-yearly lenacapavir was significantly lower than the background incidence and the incidence with F/TDF.

The Era of PrEP Choice

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On-Demand (TDF/FTC)	“2-1-1” dosing	2 pills ≥2h before sex, 1 after 24h, 1 after 48h	86%	GI upset	Labs every 3–6 mo	~\$30/mo (depends on use)
Injectable (2-month)	Apretude (cabotegravir)	Shot every 2 months (after 2nd at 4 wks)	>99%	Injection site pain, headache	Labs q4mo	~\$3,700/dose (~\$22K/yr)
Injectable (6-month)	Yeztugo (lenacapavir)	2 abdominal shots every 6 months	>99%	Injection site lumps, nausea	Labs q3–6mo	~\$14K/dose (~\$28K/yr)

Providing PrEP To Your Patients

1. Initial Clinical Assessment

- **Last unprotected sexual encounter?**
- HIV Testing
- Concomitant medications
- Screen for renal disease
- Screen for hepatitis B
- Screen for osteopenia

Providing PrEP To Your Patients

1. Initial Clinical Assessment

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 - **PrEP vs PEP**
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