



# Post Exposure Prophylaxis

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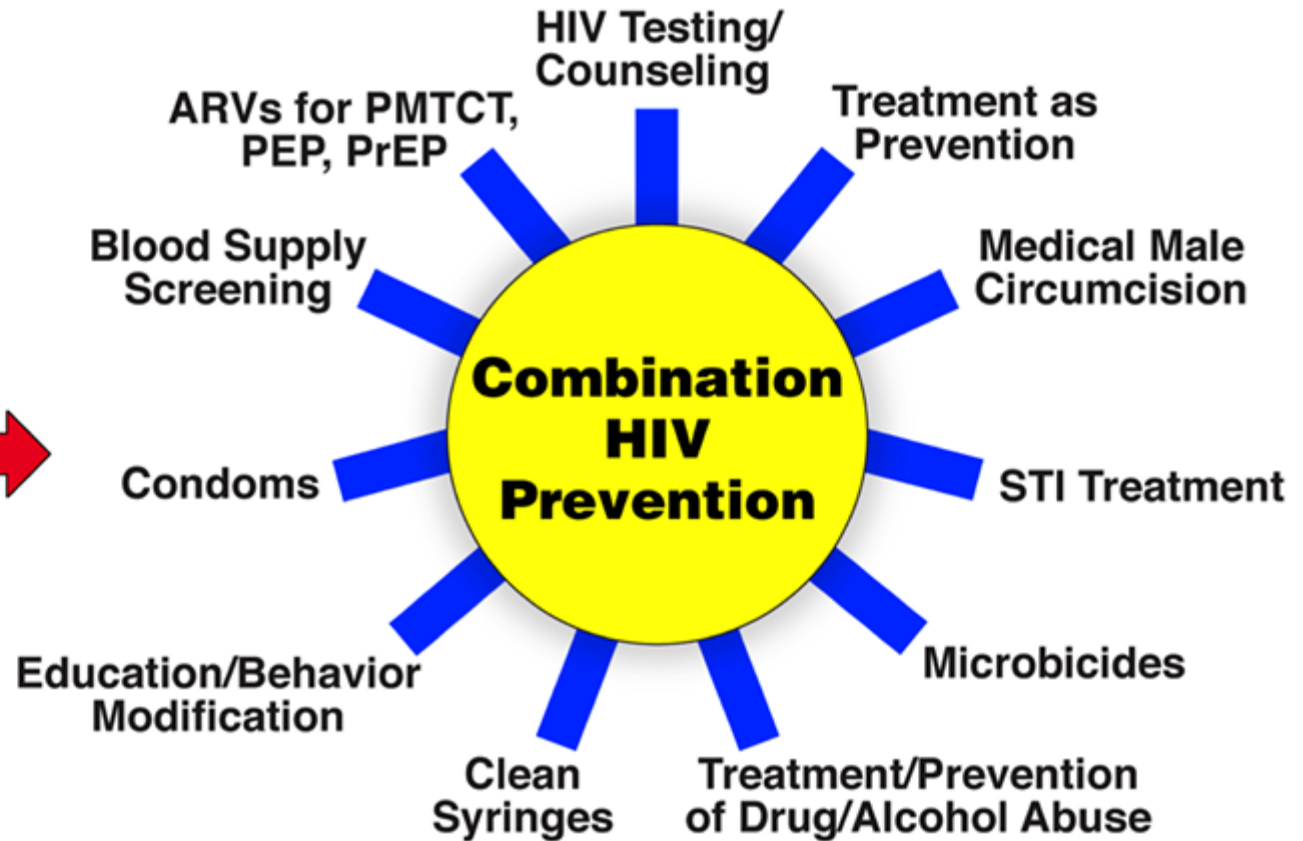
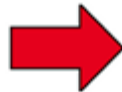
# Learning Objectives

By the end of the session, the learner will be able to:

1. Review the current best practices and guidelines regarding PEP.
2. Discuss the risks and benefits of different PEP modalities.
3. Describe strategies to facilitate the transition from PEP to PrEP
4. Discuss non HIV PEP

# Tailored Prevention Using HIV Prevention Toolkit

Provision of Tailored Prevention Services



AS Fauci/NIAID

# How soon after a potential exposure does PEP need to be started?

- a. <24 hours
- b. <2 hours
- c. <48 hours
- d. <72 hours
- e. <7 days

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- d. <72 hours**
- e. <7 days

# POST-EXPOSURE PROPHYLAXIS

- “POST” or AFTER the exposure
- Standard of Care – 3 drug regimen (typically used as HIV treatment)
- Occupational (oPEP) versus non-occupational (nPEP)
- Treatment should be initiated within **72 hours**
- “PEP” often assumed HIV PEP but non HIV PEP exists! (DoxyPEP)

## Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV— United States, 2016

from the  
Centers for Disease Control and Prevention,  
U.S. Department of Health and Human Services

## Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis

Prepared by the U.S. Public Health Service Working Group  
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Image article sources: <https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf>  
and <https://stacks.cdc.gov/view/cdc/20711>





# Who should consider taking PEP?

- PEP may be prescribed for people who are HIV negative or don't know their HIV status, and in the last 72 hours:
  - May have been exposed to HIV during sex
  - Shared needles or other equipment (works) to inject drugs
  - Experienced sexual assault
  - Has an occupational exposure



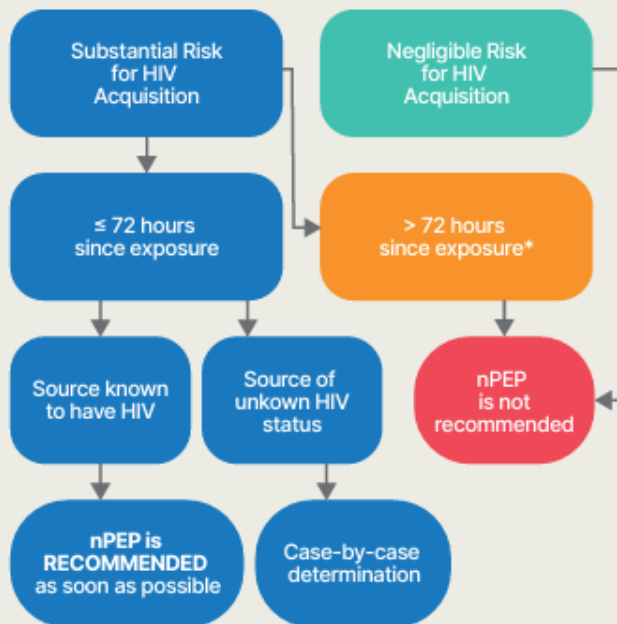
# nPEP

## Non-Occupational Post-Exposure HIV Prevention

Assessment, treatment, and follow-up recommendations for people with known or potential exposures to HIV and other infections. Health care providers should evaluate persons rapidly for nPEP when care is sought  $\leq 72$  hours after an exposure that presents a substantial risk for HIV acquisition.



### Risk Assessment



\*Some clinicians would offer nPEP on a case-by-case basis.

### Substantial Risk for HIV Acquisition

**Exposure of:** vagina, penis, rectum, eye, mouth or other mucous membrane, non-intact skin, or percutaneous contact

**With:** blood, semen, vaginal secretions, rectal secretions, breast milk, any body fluid that is visibly contaminated with blood

**When:** the source is known to have HIV

### Negligible Risk for HIV Acquisition

**Exposure of:** vagina, penis, rectum, eye, mouth or other mucous membrane, non-intact skin, or percutaneous contact

**With:** urine, nasal secretions, saliva, sweat, tears (if visible blood, see "Substantial Risk for HIV Acquisition")

**When:** regardless of the known or suspected HIV status of the source

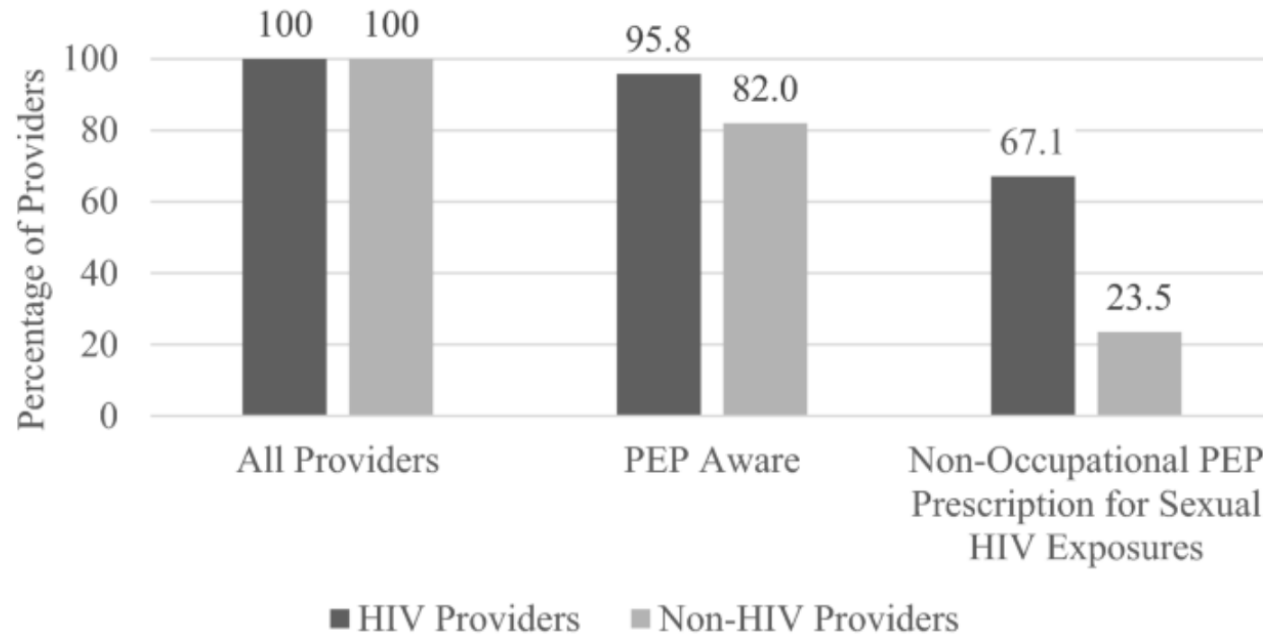
Article image source: <https://aidsetc.org/resource/npep-quick-guide-providers>





# PEP Care Cascade

Fig. 1



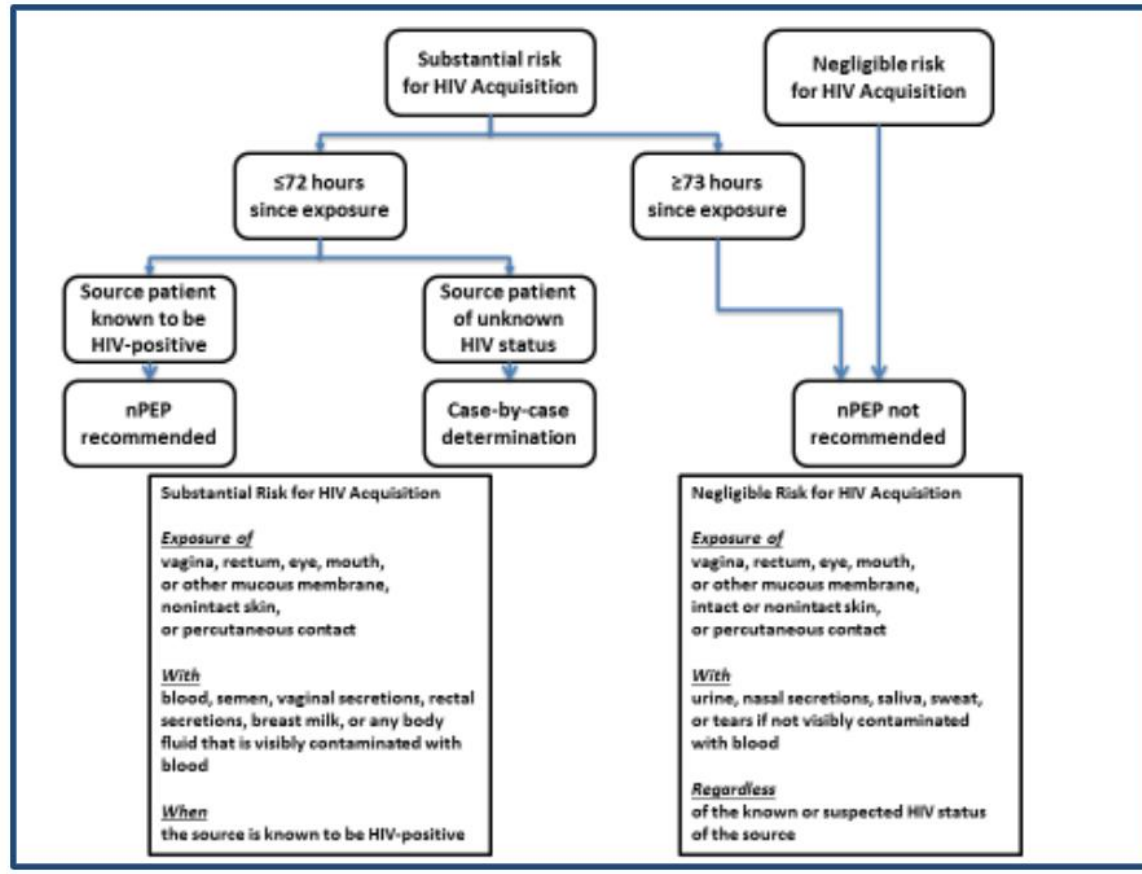
The HIV post-exposure prophylaxis (PEP) prescribing cascade for sexual HIV exposures among HIV providers ( $n = 225$ ) and non-HIV primary care providers ( $n = 255$ ) practicing within above-average HIV prevalence ZIP codes of the 10 U.S. cities with greatest overall HIV prevalence

John, S. A., Quinn, K. G., Pleuhs, B., Walsh, J. L., & Petroll, A. E. (2020). HIV Post-exposure prophylaxis (PEP) awareness and non-occupational PEP (nPEP) prescribing history among U.S. Healthcare Providers. *AIDS Behavior*, 24(11), 3124–3131. <https://doi-org.pitt.idm.oclc.org/10.1007/s10461-020-02866-6>



# Assessing Risk

Figure 1. Algorithm for evaluation and treatment of possible nonoccupational HIV exposures



Dominguez, Kenneth L. et al. (2016). Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States, 2016. <https://stacks.cdc.gov/view/cdc/38856>



**Table 1. Estimated per-act risk for acquiring human immunodeficiency virus (HIV) from an infected source, by exposure act<sup>a</sup>**

Exposure type	Rate for HIV acquisition per 10,000 exposures
<b>Parenteral</b>	
Blood transfusion	9,250
Needle sharing during injection drug use	63
Percutaneous (needlestick)	23
<b>Sexual</b>	
Receptive anal intercourse	138
Receptive penile-vaginal intercourse	8
Insertive anal intercourse	11
Insertive penile-vaginal intercourse	4
Receptive oral intercourse	Low
Insertive oral intercourse	Low
<b>Other<sup>b</sup></b>	
Biting	Negligible
Spitting	Negligible
Throwing body fluids (including semen or saliva)	Negligible
Sharing sex toys	Negligible
Source: <a href="http://www.cdc.gov/hiv/policies/law/risk.html">http://www.cdc.gov/hiv/policies/law/risk.html</a>	
<sup>a</sup> Factors that may increase the risk of HIV transmission include sexually transmitted diseases, acute and late-stage HIV infection, and high viral load. Factors that may decrease the risk include condom use, male circumcision, antiretroviral treatment, and preexposure prophylaxis. None of these factors are accounted for in the estimates presented in the table.	
<sup>b</sup> HIV transmission through these exposure routes is technically possible but unlikely and not well documented.	

Dominguez, Kenneth L. et al. (2016). Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States, 2016.

<https://stacks.cdc.gov/view/cdc/38856>



# Recommended Regimens

- oPEP guidelines (2013)
  - TDF/FTC 300/200mg po daily + RAL 400mg po bid
- nPEP guidelines (2016)
  - TDF/FTC 300/200mg po daily + RAL 400mg po bid
  - TDF/FTC 300/200mg po daily + DTG 50mg po daily
- Expert opinion
  - TAF/FTC/BIC 25/200/50mg po daily

# Surveillance Testing

	HIV	HBV	HCV	Syphilis, GC/CT	CMP
Baseline	x	x	x (Ab)	x (nPEP)	x
2 weeks					x
4-6 weeks	x		RNA (oPEP)	x (nPEP)	
3 months	x				
4 months			x (Ab)		
6 months	X (4 mo if Ag/Ab testing)	X			

Counsel patient to report any signs/symptoms of acute HIV **immediately**



# Special Considerations

- Pregnancy
- Breastfeeding
- History of gastric bypass
- Renal disease



# 2016 CDC Guidelines for Antiretroviral nPEP

Age group	Preferred/ alternative	Medication
Adults and adolescents aged ≥ 13 years, including pregnant women, with normal renal function (creatinine clearance ≥ 60 mL/min)	Preferred	A 3-drug regimen consisting of tenofovir DF 300 mg <b>and</b> fixed dose combination emtricitabine 200 mg (Truvada <sup>®</sup> ) once daily <b>with</b> raltegravir 400 mg twice daily <b>or</b> dolutegravir 50 mg once daily
	Alternative	A 3-drug regimen consisting of tenofovir DF 300 mg <b>and</b> fixed dose combination emtricitabine 200 mg (Truvada) once daily <b>with</b> darunavir 800 mg (as 2, 400-mg tablets) once daily <b>and</b> ritonavir <sup>b</sup> 100 mg once daily
Adults and adolescents aged ≥ 13 years with renal dysfunction (creatinine clearance ≤ 59 mL/min)	Preferred	A 3-drug regimen consisting of zidovudine <b>and</b> lamivudine, with both doses adjusted to degree of renal function <b>with</b> raltegravir 400 mg twice daily <b>or</b> dolutegravir 50 mg once daily
	Alternative	A 3-drug regimen consisting of zidovudine <b>and</b> lamivudine, with both doses adjusted to degree of renal function <b>with</b> darunavir 800 mg (as 2, 400-mg tablets) once daily <b>and</b> ritonavir <sup>b</sup> 100 mg once daily

For CrCl between 30 and 60 - many providers would use TAF/FTC in lieu of AZT/3TC based on expert opinion

Source image article viewable at: <https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf>



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## 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
  - Adverse events** assessed at week 4 and week 13 follow-up visits
  - HIV status** assessed at baseline, week 6, week 12
- Descriptive analysis of**
  - Participant characteristics
  - Adverse events, Adherence, HIV seroconversions

Figure 1: Recruitment card



Figure 2: Study design

**BIC/FTC/TAF was associated with high tolerability, high adherence and no HIV seroconversions, supporting use of this single tablet regimen as HIV PEP after sexual exposures.**

## 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	Value	Characteristic	Value
Age	29.3 (25.8, 34.4)	No. partners in 72h prior to PEP	1 (1,1) <sup>c</sup>
Sexual orientation and gender		Type of condomless exposure <sup>b</sup>	
Men who have sex with men	97 (81)	Anal insertive	40 (34)
Heterosexual men	16 (13)	Anal receptive w ejaculation	36 (30)
Heterosexual women	7 (6)	Anal receptive without ejaculation	21 (18)
Ethnoracial identity		Vaginal insertive	15 (13)
White	16 (20)	Vaginal receptive w ejaculation	4 (3)
Black	8 (10)	Vaginal receptive w/out ejaculation	3 (3)
Asian	34 (43)	Partner's reported HIV status	
Latin American	13 (16)	Positive	12 (10)
Identity other than these or mixed	9 (11)	Negative or unknown	107 (90)
Comorbidities in ≥5% of sample		Initially prescribed PEP regimen	
ADHD	6 (5)	DTG + TDF/FTC	106 (89)
Anxiety/depression	7 (6)	RAL + TDF/FTC	2 (2)
No. times previously used PEP		BIC/FTC/TAF	11 (9)
0	91 (77)	Days of PEP before BIC/FTC/TAF	2 (1, 3)

## RESULTS

- Tolerability:** Only 10% experienced adverse events of grade ≥2 severity

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

Adverse event	Overall N (% of participants)	Severity grade ≥2 N (% of participants)	Any grade, at least possibly related to study drug N (% of participants)
Anorexia	3 (3%)	0 (0%)	3 (3%)
Diarrhea	11(8%)	4 (3%)	10 (8%)
Dizziness	5 (4%)	0 (0%)	5 (4%)
Fatigue	24(20%)	2 (2%)	24 (20%)
Headache	9 (8%)	0 (0%)	9 (8%)
Nausea	14 (12%)	0 (0%)	14 (12%)
Sleep disturbance	6 (4%)	0 (0%)	6 (4%)

- Adherence:** 90/102 or 88% of participants with available data reported completing ≥28 days of PEP

Figure 3: Total number of days of PEP taken



## 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

> J Acquir Immune Defic Syndr. 2022 May 1;90(1):27-32. doi: 10.1097/QAI.0000000000002912.

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

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Affiliations + expand

PMID: 34991141 DOI: 10.1097/QAI.0000000000002912

## Abstract

**Background:** Antiretroviral post-exposure prophylaxis (PEP) is recommended to prevent HIV infection after a high-risk exposure, but current regimens have presented challenges in tolerability, regimen completion, and potential drug-drug interactions. Because coformulated bictegravir, emtricitabine, and tenofovir alafenamide [BIC/FTC/tenofovir alafenamide (TAF)] is effective for HIV treatment, it was evaluated for use for PEP.

# Access Issues

## Gilead Advancing Access (1-800-226-2056)

- Descovy (Emtricitabine / Tenofovir alafenamide )
- Truvada (Emtricitabine / Tenofovir DF)
- Biktarvy (Bictegravir / Emtricitabine / Tenofovir alafenamide)

## ViiV Connect (1-844-588-3288)

- Tivicay (Dolutegravir)

## Merck Helps (1-800-727-5400)

- Isentress (Raltegravir)

Many EDs also have 3-4 days starter packs of PEP prepositioned in the clinic space



# Novel Approaches to PEP: PIP

**NOW THERE IS A BUFFET OF HIV MEDICAL PREVENTION OPTIONS, INCLUDING PIP: PEP-IN-POCKET!**



Zero-to-few  
exposures



Many exposures

From Bogoch et al, IDWeek 2023

**PIP = HIV POST-EXPOSURE PROPHYLAXIS (PEP)-IN-POCKET**

# Current HIV Prevention Modalities

**PrEP** is terrific...for those with semi-frequent exposures

- Pill vs injection burden
- On-demand PrEP: Effectiveness for 1-3 exposures per year? Or unanticipated exposures?

**PEP** works well...if you can get it

- Tremendous barriers to access
- Cost, knowledge, availability, follow up, stigma



# PEP in Pocket (PIP)

- Biomedical prevention modality for those with **LOW** frequency of **HIGH** risk exposures
- Pro-active prescription for 28 days of guidelines endorsed PEP
- Patients self initiate following exposure
- Follow up in clinic on a non urgent basis
- Potential to reduce barriers to access (no ED visit, reduction in cost, greater patient autonomy)
- NB - currently standard of care locally (major barrier would be insurance coverage)

Billick, Maxime J. MDCM<sup>a</sup>; Fisher, Karla N. MSc<sup>b</sup>; Myers, Samantha BSc<sup>c</sup>; Tan, Darrell H. S. MD, PhD<sup>a,c</sup>; Bogoch, Isaac I. MD, MS<sup>a,b,d</sup>. Brief Report: Outcomes of Individuals Using HIV Postexposure Prophylaxis-In-Pocket (“PIP”) for Low-Frequency, High-Risk Exposures in Toronto, Canada. *JAIDS Journal of Acquired Immune Deficiency Syndromes* 94(3):p 211-213, November 1, 2023. | DOI: 10.1097/QAI.0000000000003282



A 24yo cis M presents for his follow up visit after initiating PEP for a possible sexual exposure. It's his second course in 4 months. When should he have repeat HIV testing to transition to PrEP?

- a. 2 weeks after exposure
- b. 6 weeks after exposure (2 weeks after finishing PEP)
- c. 4 weeks after exposure (end of PEP course)
- d. 12 weeks after exposure (8 weeks after finishing PEP)

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# PEP to PrEP

- Good option for people at ongoing risk of HIV acquisition with a recent high risk exposure
  - Those who request PrEP and have a recent high risk encounter in the last 72 hours
  - Those who request repeated courses of PEP

# PEP to PrEP

- Repeat HIV Ag/Ab testing at end of 28 day PEP course
- If testing is negative AND no signs/symptoms of acute infection, prescribe PrEP regimen (oral or injectable)
- If rapid test is positive or there are signs/symptoms of acute infection, continue 3 drug regimen until HIV status is confirmed

# Review of FDA Approved HIV Pre-exposure Prophylaxis

- 2012: Daily FTC/TDF approved for HIV prevention in adults and adolescents over 35 kg/77 lbs
- 2019: Daily FTC/TAF approved for HIV prevention in people **whose risk factor is not receptive vaginal or frontal sex**
- 2021: Bimonthly injectable cabotegravir approved for prevention of HIV in adults and adolescents





# PEP Consultation Resources

## PEP: Post-Exposure Prophylaxis



### Timely answers for urgent exposure management

Get rapid, expert guidance in managing healthcare worker exposures to HIV and hepatitis B and C, including recommendations on when and how to initiate PEP through our online Quick Guide for urgent occupational PEP decision-making, or from experienced clinicians on our telephone consultation service. Note that our hours have changed because of funding limitations. ***We cannot accept calls from unknown numbers. Please unblock your phone prior to calling the PEpline.***

Alert: Some calls to the PEpline using a Cisco phone may not go through. Please use another phone or cell phone. We are addressing this issue.

Hours of operation for occupational PEP consultation are **11 a.m. – 8 p.m. ET (seven days a week)**. If you are trying to reach us regarding an occupational PEP question outside of these hours, please check out our [PEP Quick Guide for Occupational Exposures](#).

Hours of operation for non-occupational PEP consultation are **9 a.m. – 8 p.m. ET Monday – Friday, and 11 a.m. – 8 p.m. ET on weekends & holidays**.  
**(888) 448-4911**

CALL

See our [PEP Quick Guide](#) for answers to the most frequently asked questions.

# Case

- Kate is a 34 year old sex worker who takes oral PrEP (FTC/TDF) daily and started 6 months ago.
- She reports good adherence and denies missed doses
- She reports that she was with a client and the condom broke while she was having receptive vaginal sex
- Should she consider PEP?

# Now for a challenging case!

- Caleb is a 22 year old bisexual male who has a history of treated rectal chlamydia a year ago who also started LA cabotegravir 6 months ago. He received only one injection and unfortunately was lost to follow up. He is not on oral PrEP.
- He presents to your clinic stating that about 24 hours ago he had condomless receptive anal sex with another male partner who he found out was living with HIV and not on antiretroviral therapy.

Should he consider post-exposure prophylaxis?

What tests would be important before he starts PEP?

# Long Acting Injectable PrEP

- CAB 600mg IM gluteal injection every two months
- Superior to TDF/FTC for PrEP
- Able to use in CrCl <30 mL/min
- No effect on hepatitis B
- Unknown time to efficacy
- Review signs/symptoms of acute retroviral syndrome
- HIV Ag/Ab and **HIV-1 RNA** every 2 months

<https://www.cdc.gov/hivnexus/media/pdfs/2024/04/cdc-lsht-prevention-brochure-clinicians-quick-guide-what-is-injectable-hiv-prep.pdf>

# Challenges of Long Acting Injectables

- Advent of long acting injectable PrEP (cabotegravir) poses a challenge for individuals who are lost-to-follow-up, yet have exposure to HIV
- Individuals who are non adherent to LAI PrEP experience the “CAB PK tail” – low but non-protective levels of cabotegravir
- Individuals at higher risk for development of resistance if seroconversion occurs
- This individual may benefit from non-integrase based PEP because of the risk for integrase resistance.



# Long-Acting Early Viral Inhibition Syndrome (LEVI Syndrome)

- 6 infections occurred in HPTN 083 (2,282 participants) despite on-time injections
- Diminished/delayed antibody production
- HIV RNA levels may be low or undetectable but do detect infection earlier than Ag/Ab assays
- Delayed detection can lead to development of drug resistance



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

	AHI	LEVI
<b>Cause</b>	Phase of natural HIV infection	Long-acting anti-viral PrEP agent (prototype: CAB-LA)
<b>Onset</b>	New infection	Infection during PrEP Initiation of PrEP agent during acute/early infection
<b>Viral replication</b>	Explosive	Smoldering
<b>Symptoms</b>	Fever, chills, rash, night sweats, muscle aches, sore throat, fatigue, swollen glands	Protean, often no symptoms reported
<b>Detection</b>	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)
<b>Duration</b>	1-2 weeks (until Ab detection)	Months (until viral breakthrough, cessation of anti-viral exposure or ART start)
<b>Persistence</b>	Rare	Weeks-months after anti-viral agent is discontinued
<b>Transmission</b>	Very likely	Unlikely (except possibly through blood transfusion)
<b>Drug resistance</b>	No (unless transmitted)	Yes (can emerge early when viral load is low)

Eshleman SH et al. CROI 2023. Abstract #160



# Additional Thoughts

- STI testing should be offered routinely to all those on PrEP
  - Guidelines recommend bacterial STI testing every 3-4 months for MSM and TGW who have sex with men and every 6 months for heterosexual cisgender men and women
  - Consider offer testing at each visit to all patients
- People using PEP/PrEP may also benefit from DoxyPEP
  - Doxycycline taken after sexual encounters to decrease the risk of syphilis, chlamydia, and gonorrhea

Bachmann LH, Barbee LA, Chan P, et al. CDC Clinical Guidelines on the Use of Doxycycline Postexposure Prophylaxis for Bacterial Sexually Transmitted Infection Prevention, United States, 2024. MMWR Recomm Rep 2024;73(No. RR-2):1–8. DOI: <http://dx.doi.org/10.15585/mmwr.rr7302a1>.





# CDC Clinical Guidelines on the Use of Doxycycline Postexposure Prophylaxis for Bacterial Sexually Transmitted Infection Prevention, United States, 2024

*Recommendations and Reports* / June 6, 2024 / 73(2);1–8

[Print](#)

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# CDC Guidance for DoxyPEP as STI prevention

Recommendation*	Strength of recommendation and quality of evidence <sup>†</sup>
<ul style="list-style-type: none"> <li>Providers should counsel all gay, bisexual, and other men who have sex with men (MSM) and transgender women (TGW) with a history of at least one bacterial sexually transmitted infection (STI) (specifically, syphilis, chlamydia or gonorrhea) during the past 12 months about the benefits and harms of using doxycycline (any formulation) 200 mg once within 72 hours (not to exceed 200 mg per 24 hours) of oral, vaginal, or anal sex and should offer doxycycline postexposure prophylaxis (doxy PEP) through shared decision-making. Ongoing need for doxy PEP should be assessed every 3–6 months.</li> </ul>	<p style="text-align: center;">AI</p> <p style="text-align: center;">High-quality evidence supports this strong recommendation to counsel MSM and TGW and offer doxy PEP.</p>
<ul style="list-style-type: none"> <li>No recommendation can be given at this time on the use of doxy PEP for cisgender women, cisgender heterosexual men, transgender men, and other queer and nonbinary persons.</li> </ul>	<p style="text-align: center;">Evidence is insufficient to assess the balance of benefits and harms of the use of doxy PEP</p>

Bachmann LH, Barbee LA, Chan P, et al. CDC Clinical Guidelines on the Use of Doxycycline Postexposure Prophylaxis for Bacterial Sexually Transmitted Infection Prevention, United States, 2024. MMWR Recomm Rep 2024;73(No. RR-2):1–8. DOI: <http://dx.doi.org/10.15585/mmwr.rr7302a1>.



# Summary

- PEP consists of a three drug combination given after HIV exposure
- Standard PEP is FTC/TDF + integrase inhibitor
- Should be given within 72 hours of exposure
- Duration of PEP is 28 days
- PEP can serve as a bridge to PrEP
- CDC recently release guidelines on DoxyPEP, a form of non-PEP effective against bacterial STIs

