

HIV Pre-exposure Prophylaxis and Post-Exposure Prophylaxis in Primary Care: Stepping Into PrEP and PEP

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Dr. Grivois-Shah is a graduate of the University of Illinois College of Medicine, Chicago. He completed his family medicine residency at Advocate Illinois Masonic Medical Center Family Medicine Residency Program, Chicago, and earned his Master of Public Health (MPH) degree from the University of Illinois-Chicago, and his Masters in Business Administration (MBA) from the University of Arizona. Dr. Grivois-Shah serves as Medical Director of Alvernon Family Medicine which trains 24 residents, and as Medical Director of the U of A Mobile Health Program.

Dr. Grivois-Shah practices full-spectrum family medicine, from birth to end of life. He has worked in a variety of settings, from Cook County Health community clinics and an FQHC network in Chicago, to his current academic hospital-based practice.

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Learning Objectives

1. Outline the 2016 updated CDC guidelines regarding non-occupational post-exposure prophylaxis for HIV prevention.
2. Outline the 2014 US Public Health Service clinical practice guidelines on pre-exposure prophylaxis for the prevention of HIV infection.
3. Develop a strategy for screening of patients in the ED and urgent care settings for eligibility for post-exposure prophylaxis to prevent HIV infection.
4. Develop strategy and knowledge base for either providing PrEP care in family medicine clinic or identifying and referring to local resources for PrEP care for patients in high risk groups for HIV acquisition.

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Additional Learning Objectives

1. Increase comfort identifying patients at risk for HIV and counseling on the risks and benefits of PrEP usage
2. Improve ability to appropriately prescribe and monitor PrEP usage
3. Identify strategies to increase patient adherence to PrEP
4. Review special population considerations when prescribing PrEP
5. Increase awareness and usage of nPEP in appropriate populations


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Audience Engagement System

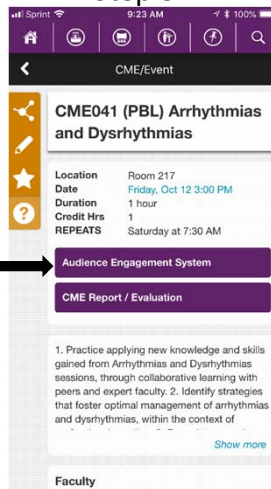
Step 1



Step 2



Step 3



The image illustrates the Audience Engagement System through three steps. Step 1 shows the app's dashboard with a grid of icons for navigation, including My Schedule, CME/Events, Faculty, Exhibit Hall, Maps, Event Pulse, Claim CME, Attendee Profiles, Social Media, and Local Places. Step 2 shows the CME/Events screen with a calendar view and a list of events, with an arrow pointing to the first event: CME041 (PBL) Arrhythmias and Dysrhythmias. Step 3 shows the details for CME041, including location (Room 217), date (Friday, Oct 12 3:00 PM), duration (1 hour), credit hours (1), and repeats (Saturday at 7:30 AM). The details screen also features buttons for Audience Engagement System and CME Report / Evaluation, and a list of learning objectives.

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AES Question #1

What is your experience with PrEP?

- A. I have never prescribed PrEP before
- B. I prescribe PrEP infrequently, and hoping to get more comfortable with this
- C. I prescribe PrEP regularly, and want to affirm my knowledge of PrEP

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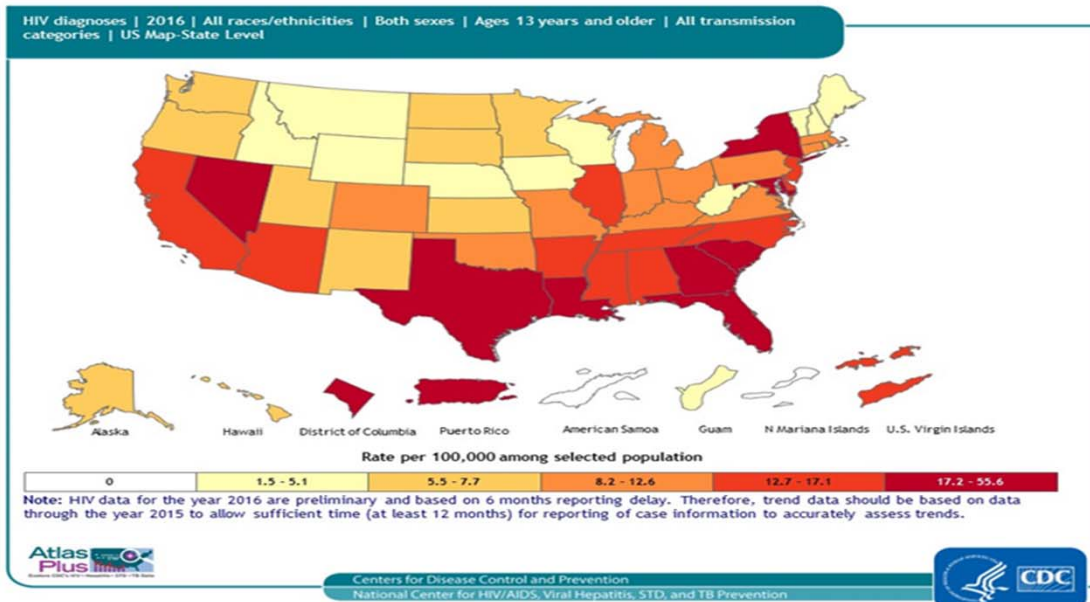
Outline

- I. Introduction to PrEP
 - A. HIV in America
 - B. What is PrEP?
 - C. Identifying patients at risk for HIV
 - D. Efficacy of PrEP
- II. Prescribing PrEP
 - A. Initiation and Monitoring
 - B. Safety
 - C. Improving adherence
- III. PrEP in Special Populations
 - A. Women
 - B. Adolescents
 - C. Patients with Chronic Disease
- IV. nPEP
 - A. Identifying patients
 - B. Prescribing
 - C. Monitoring
- V. Practice Management

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Isn't HIV on the decline? Why talk about it?

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CDC HIV Surveillance Report <https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>

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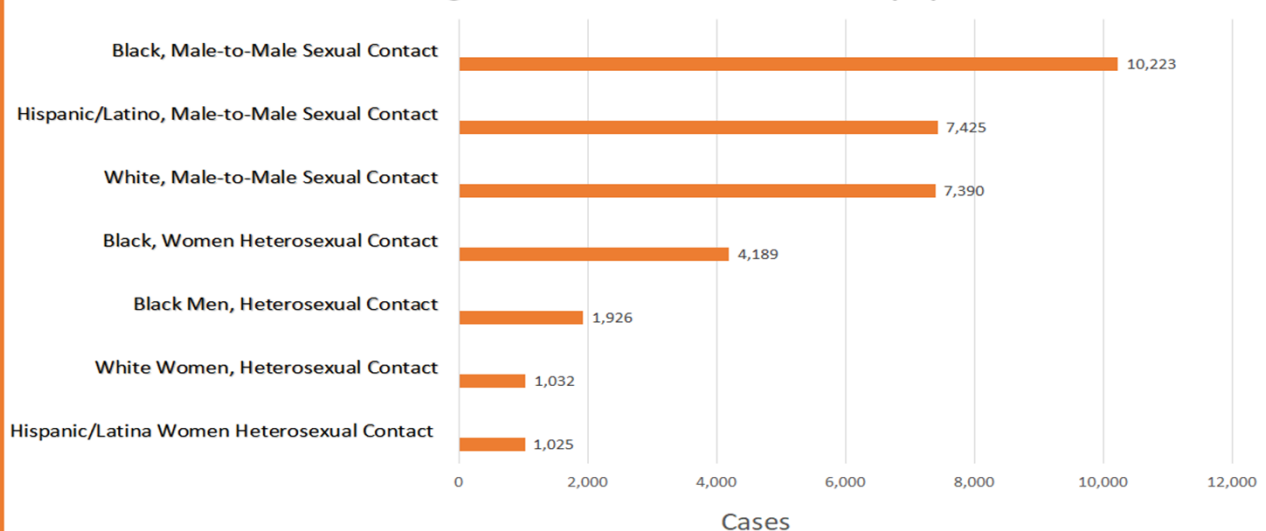
AES Question #2

Which group has the LOWEST new cases of HIV diagnosis?

- A. African American (AA) men who have sex with men (MSM)
- B. Latino MSM
- C. White MSM
- D. AA women who have sex with men only (WSM)
- E. AA men who have sex with women only (MSW)

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2016 US HIV Diagnoses For Most Affected Subpopulations



CDC HIV Surveillance Report <https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>

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How can we prevent HIV transmission?

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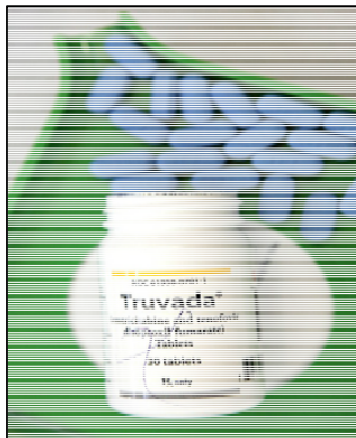
What is Pre-Exposure Prophylaxis (PrEP)?

- Highly effective method to reduce HIV transmission
 - Once daily fixed dosage combination nucleoside reverse transcriptase inhibitors
 - Tenofovir disoproxil fumarate (TDF) 300mg and Emtricitabine (EFT) 200mg
 - Trade name Truvada[®]



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What is Pre-Exposure Prophylaxis (PrEP)?



- Tenofovir disoproxil fumarate 300mg and Emtricitabine 200mg
 - Approved by the FDA in 2012
 - Recommended for adults with substantial risk of recurring HIV exposure (sexual or injection drug use)
 - Long plasma (10 to 17 hours) and intracellular (39¹ and 150² hours) half-lives
 - High vaginal and rectal tissues penetration

FDA Drug Approval Package
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/021752s000_TruvadaTOC.cfm; Grant RM, et al. N Engl J Med. 2010; 363(27): 2587-2599

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What Is Primary Care's Role In Preventing HIV?

Outcome to Prevent	Intervention	Number Needed To Treat
Death from colorectal cancer	Annual fecal occult blood testing	4551
Stroke in women with no previous CV disease	Aspirin 81mg daily	411
Myocardial infarction in patient's with hypertension and average cholesterol	Atorvastatin 10mg daily	100
HIV infection in MSM	TDF/FTC 300/200mg daily	13

Mandal JS, et al. N Engl J Med. 1993; 328:1365-137; Berger JS, et al. JAMA. 2006; 295: 306-313; Sever PS, et al. Lancet. 2003; 361:1149-1158; McCormack S; et al. CROI 2015

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1.2 million people living with HIV in the United States unaware of their status:

25% of MSM

145,000 active prescriptions for PrEP

Urban areas with higher use:

New York City:
30% of MSM use PrEP

CDC HIV Surveillance Report <https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>
Grant RM, et al. N Engl J Med. 2012; 367(5): 399-410.

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Which patients should I consider for PrEP?

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AES Question #3

Which of the following has the HIGHEST risk for acquiring HIV from an infected source?

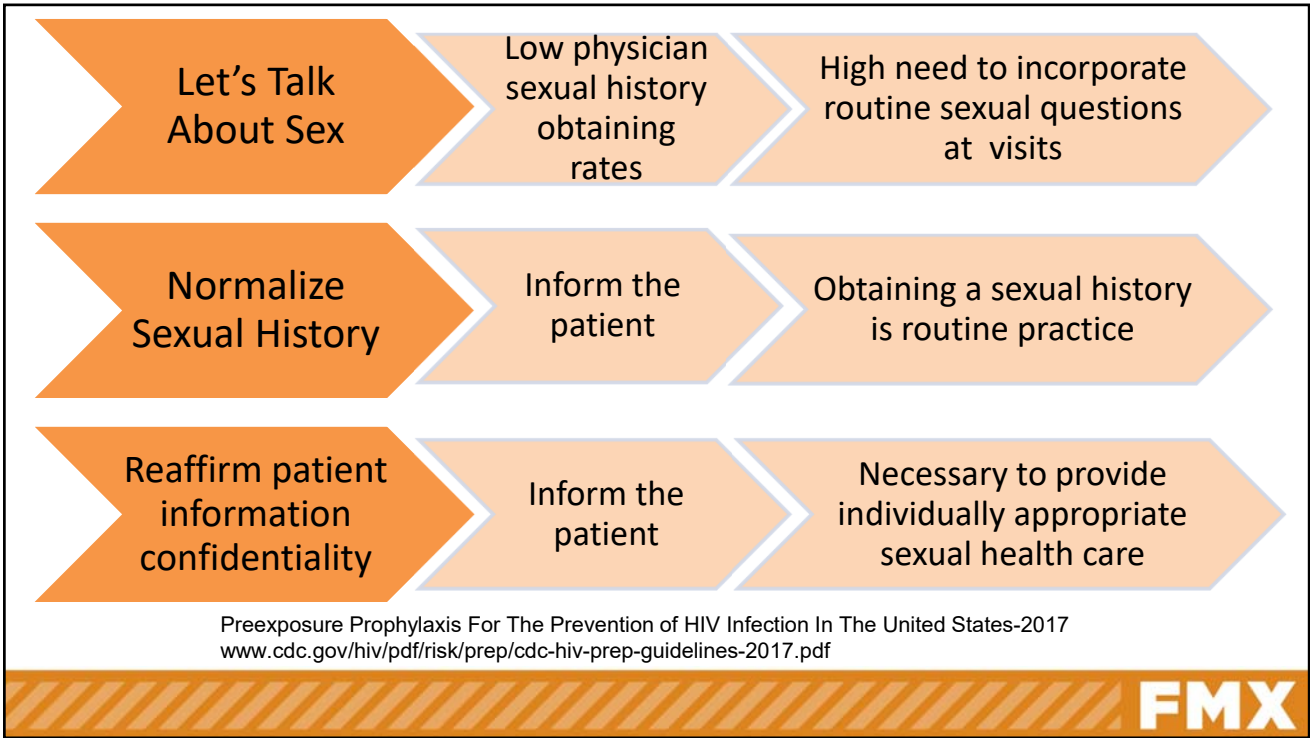
- A. Sharing needles during injection drug use
- B. Receptive anal intercourse
- C. Receptive penile-vaginal intercourse
- D. Sharing sex toys

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Estimate Per Act Risk For Acquiring HIV For A Source	
Type of Exposure	Risk per 10,000 Exposures
Parental	
Needle Sharing	63
Percutaneous (Needle Stick)	23
Sexual	
Receptive anal intercourse	138
Receptive penile-vaginal intercourse	8
Insertive anal intercourse	11
Insertive penile-vaginal intercourse	4
Receptive and Insertive oral intercourse	Low
Other	
Sharing sex toys	Negligible

CDC HIV Risk Behaviors <https://www.cdc.gov/hiv/risk/estimates/riskbehaviors.html>

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What Questions Assist With Sex Risk Determination?

In the past 6 months:
Have you had sex with men, women or both?
How many sexual partners have you had in the last 6 months?
How many times did you have vaginal or anal sex when neither you nor your partner wore a condom?
How many of your partners were HIV positive?
(if any positive) With these HIV positive partners, how many times did you have vaginal or anal sex without a condom?
In the past six month how many times have you been diagnosed with chlamydia, syphilis or gonorrhea?
Have you used methamphetamines (such as crystal or speed)?

Preexposure Prophylaxis For The Prevention of HIV Infection In The United States-2017
www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf

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HIV in Injection Drug Users (IDU)

IDU accounted for 8% of 2010 HIV infection incidents



National HIV Behavioral Surveillance System found:

- 34% IDU report sharing syringes
- 58% IDU report sharing injection equipment

CDC HIV Surveillance Report <https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>

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HIV in Injection Drug Users (IDU)

Risk Behavior Assessment For Injection Drug Users

Have you ever injected drugs that were not prescribed to you by a clinician?

(if yes) When did you last inject nonprescription drugs?

In the past 6 months, have you injected by using needles, syringes or other drug preparation equipment used by another person?

In the past 6 months, have you been in a methadone or other medication based drug program?

Preexposure Prophylaxis For The Prevention of HIV Infection In The United States-2017
www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf

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Identifying Patients for PrEP

Men	Women	Injection Drug Users
<ul style="list-style-type: none"> Sexually active with other men Non-monogamous Any anal sex without a condom 	<ul style="list-style-type: none"> Sexually active with high risk partner (IDU, MSM), with infrequent condom use 	<ul style="list-style-type: none"> Injection of drugs not prescribed by a clinician
<ul style="list-style-type: none"> Sexually active with high risk partner (IDU, CSW) with infrequent condom use 	Commercial Sex Worker (CSW)	<ul style="list-style-type: none"> Sharing of drugs or equipment
<ul style="list-style-type: none"> Serodiscordant partner 	<ul style="list-style-type: none"> Serodiscordant partner 	<ul style="list-style-type: none"> Risk of sexual acquisition
<ul style="list-style-type: none"> Bacterial STI (last 6 months) 	<ul style="list-style-type: none"> Bacterial STI (last 6 months) 	<ul style="list-style-type: none"> STI (last 6 months)

Preexposure Prophylaxis For The Prevention of HIV Infection In The United States-2017
www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf

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Does PrEP really work?

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Yes, if the patient takes it...

Efficacy Correlated to Medication Adherence	iPrEX Study	Kaiser Permanente Study
<ul style="list-style-type: none"> • 92-100% HIV risk reduction with detectable serum drug levels 	<ul style="list-style-type: none"> • 44% HIV reduction rate • Drug level concentrations consistent with 4 times weekly usage 	<ul style="list-style-type: none"> • 100% efficacy with 92% overall medication adherence rates • Zero HIV seroconversions

Riddell IV J. JAMA 2018; 319(12): 1261-1268; Marcus JL, et al. J Acquir Immune Defic Syndr 2016; 73(5): 540-546; Molina JM, et al. N Engl J Med 2015; 373(23): 2237-2246, Haberer JE. Curr Opin HIV AIDS. 2016;11(1):10-17

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What Major PrEP Randomized Trials Exist?

iPrEx	IPERGAY	PROUD
<ul style="list-style-type: none"> • Multi-country study • HIV negative MSM (2499) • TDF/emtricitabine vs placebo • 44% HIV reduction rate 	<ul style="list-style-type: none"> • HIV negative MSM • Complex on demand TDF/emtricitabine vs placebo • 86% HIV reduction rate 	<ul style="list-style-type: none"> • HIV negative MSM • TDF/emtricitabine vs HIV prevention • 86% HIV reduction rate

Grant RM, et al. N Engl J Med. 2010; 363(27): 2587-2599; Baeten DD, et al. N Engl J Med. 2012; 367(5): 399-410; Molina JM, et al. N Engl J Med. 2015; 373(23): 2237-2246; McCormack S, et al. Lancet 2016; 387 (10013): 53-60; VanDamme L, et al. N Engl J Med 2012; 367: 411-422; Marrazzo JM, et al. N Engl J Med 2015; 372(6): 509-518

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What Major PrEP Randomized Trials Exist?

Bangkok Tenofovir Study

- Injection drug users
- Directly observed vs unobserved vs placebo
- Directly observed group 74% reduction rates

Partners PrEP

- Serodiscordant heterosexual partners
- TDF/emtricitabine vs placebo
- 75% HIV reduction in combined arm

Thigpen MC, et al. N Engl J Med. 2012; 367(5): 423-434; Choopanya K, et al. Lancet 2013; 381: 2083-2090



Is PrEP Equally Effective in Men and Women?

Tenofovir's Effects		
	Colorectal Tissue	Cervicovaginal Tissue
Half- life	Detectable for 14 days	71 hours
Concentration	100 fold higher	
Protective Intracellular Levels Onset	7 days of therapy	21 days of therapy
Adherence Needed to Reduce HIV Transmission	4 days per week	Daily usage

Patterson KB et al, Sci Transl Med. 2011; 5(112): 112re4; Anderson PL et al. MMWR. 2015; 64: 1291-1295; Baeten DD, et al N Engl J Med. 2012; 367(5): 399-410; Thigpen MC et al N Engl J Med. 2012; 367(5): 423-434



What should I order before starting PrEP?



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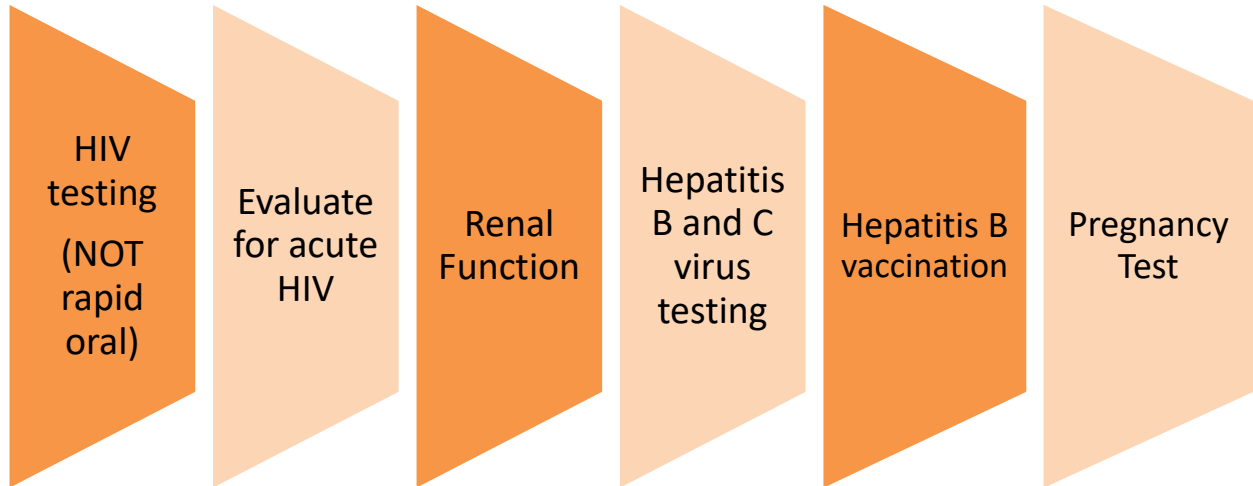
AES Question #4

What should you order in ALL patients before starting PrEP?

- A. Renal Function Test
- B. Liver Function Test
- C. PPD / Quantiferon
- D. Bone Density Scan

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What's Needed Before Initiating PrEP?



Preexposure Prophylaxis For The Prevention of HIV Infection In The United States-2017
www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf

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What Are The Clinical Signs of Acute HIV Infection?

Features	Overall (N=375)
Fever	75
Fatigue	68
Myalgia	49
Skin rash	48
Headache	45
Pharyngitis	40
Cervical adenopathy	39
Arthralgia	30
Night sweats	28
Diarrhea	27

Preexposure Prophylaxis For The Prevention of HIV Infection In The United States-2017 www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf

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What Tests Are Required To Initiate PrEP?

STI Testing	Potential Specimen Depending on Sexual Behavior
Gonorrhea and Chlamydia nucleic acid amplification test	First Catch Urine (or direct cervical or urethral specimen)
	Pharyngeal Swab*
	Rectal Swab*
Syphilis	Serum

* Consider self-swab by patient

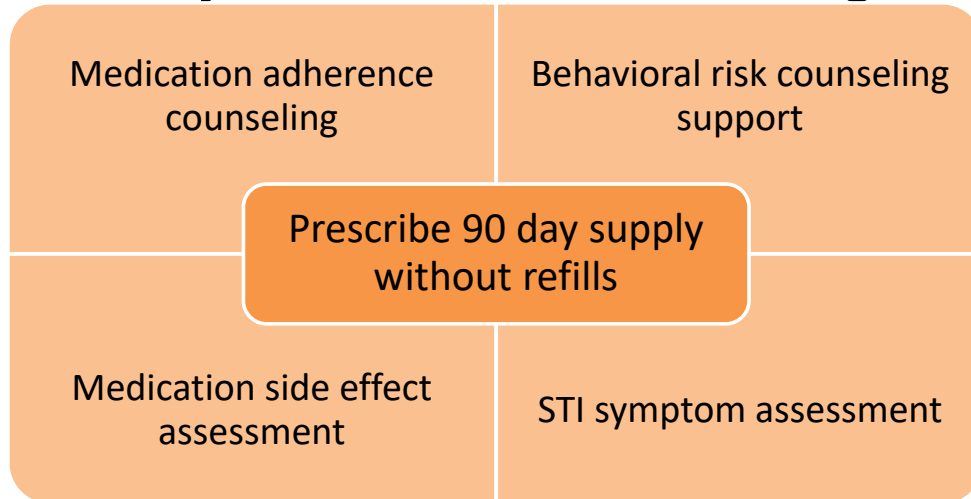
Preexposure Prophylaxis For The Prevention of HIV Infection In The United States-2017
www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf

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How often should I see my patients on PrEP? What should I check periodically?

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Key's To PrEP Prescribing



Preexposure Prophylaxis For The Prevention of HIV Infection In The United States-2017
www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf

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What Monitoring Is Recommended?

All PreEP Users (Q3 months)

- HIV, GC and CT test
- Renal function Q3-6 months

Women (Q3 months)

- Pregnancy
- Discuss pregnancy intent

IDU (Q3 months)

- Discuss access to clean needles
- Discuss drug treatment services

Preexposure Prophylaxis For The Prevention of HIV Infection In The United States-2017 www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf

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Why Regular Screening for STIs?

- PrEP usage independently associated with new STI
 - 30% diagnosed with at least one STI at 12 months
- Majority of pharyngeal and rectal Gonorrhea and Chlamydia are asymptomatic
 - 65% cases of Gonorrhea and 50% of Chlamydia among MSM
 - 10% of Chlamydia and 31% of Gonorrhea in women

Riddel IV J. JAMA 2018; 319(12): 126-1268; Mayer, KH et. al. Open Forum Infect Dis. 2017 Oct 8;4(4)

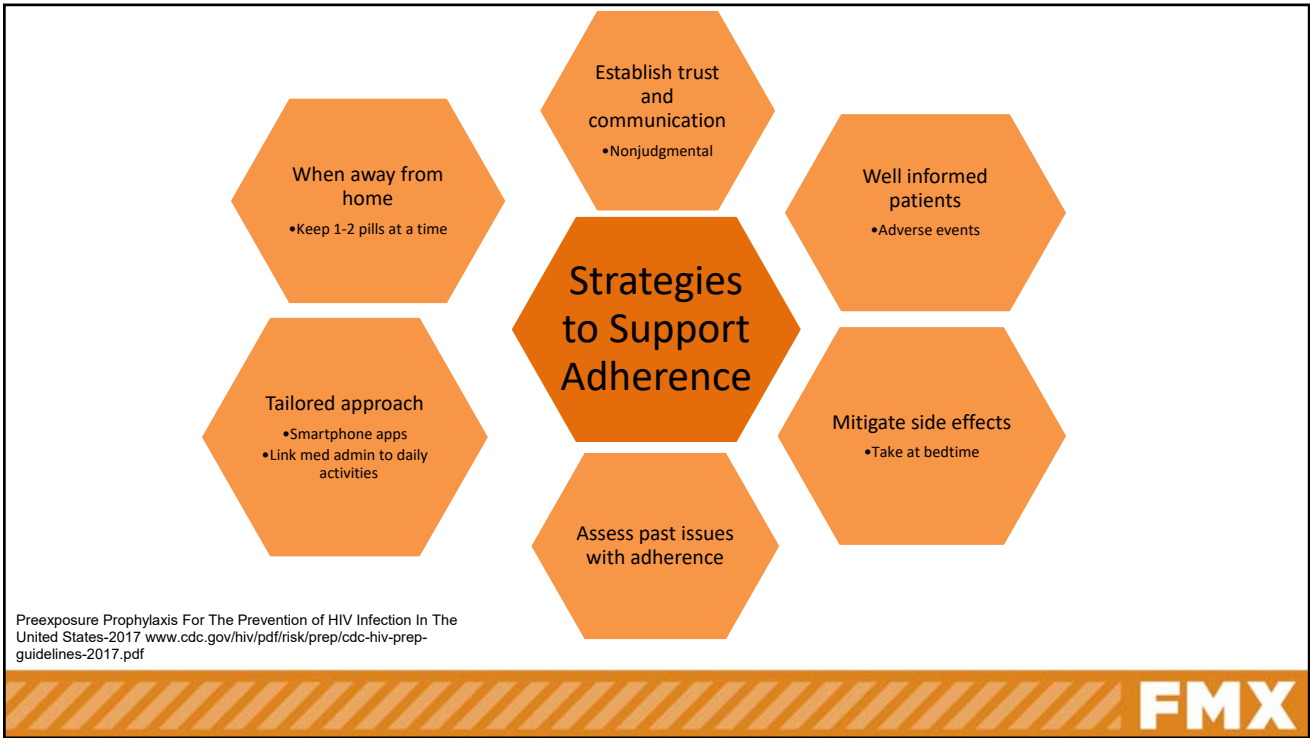
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Does PrEP Affect Sexual Behaviors?

- No increase in high risk behavior
 - No change in the number of sexual partners
 - No change in condom usage
 - Why STD rates higher?
 - Not randomized?
 - More frequent testing?

Marcus JL, PLoS One. 2013;8(12)

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How well is PrEP tolerated by patients? Is PrEP safe?

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What Are the Side Effects of Truvada

Start Syndrome

Nausea
Vomiting
Cramps

Well tolerated

Bone Density

~1% decrease in
bone density

No increase in
atraumatic
fractures

Renal Function

Small decrease
in CrCl

Contraindicated
in CrCl<60

Preexposure Prophylaxis For The Prevention of HIV Infection In The United States-2017
www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf

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How Safe is Truvada® ?

- 2016 narrative review found
 - Truvada compared to Aspirin in safety



Kojima N, et al. Open Forum Infect Dis. 2016 6;3(1)

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What about PrEP in special populations?

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AES Question #5

What is true about PrEP?

- A. PrEP affects hormone contraception effectiveness
- B. PrEP is contraindicated in patients with Hepatitis B
- C. PrEP is approved for adolescent patients
- D. PrEP dosing can be adjusted for patients with renal failure

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PrEP In Women

Contraception

- No effect on contraceptive effectiveness

Pregnancy

- No adverse outcomes
- No increase birth defects
- Pregnancy registry

Breastfeeding

- Unclear on infant effects

Preexposure Prophylaxis For The Prevention of HIV Infection In The United States-201; www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf

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Can PrEP Be Used In Adolescents?

- FDA approved (2018)
- Well teen visit:
 - Discuss HIV screening with sexually active teens
- PrEP recommended in:
 - At risk sexually active adolescents
 - Weigh at least 35kg

FDA Drug Approval Package
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/021752s000_TruvadaTOC.cfm

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Adolescents Medication Adherence

- Lower medication adherence rates
- Monthly visits recommended
 - Study demonstrated lower adherence with quarterly visits



Hosek SS, et al. Acquir Immune Defic Syndro. 2013;62(4):447-456; Machado DM, et al. Adolesc Health Med Therap. 2017; 8:137-148

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Hepatitis B and PrEP

- TDF/FTC active against HBV
 - May prevent significant liver disease
- Quantitative HBV DNA needed:
 - Prior to PrEP initiation and every 6-12 months
- Sub-specialty referral needed

Preexposure Prophylaxis For The Prevention of HIV Infection In The United States-2017
www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf

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What about my patients who see me after their potential exposure to HIV?

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Nonoccupational Postexposure Prophylaxis (nPEP)

- Administer within 72 hours of:
 - HIV sexual exposure
 - HIV injection drug usage exposure
- 28 day course of treatment
- Safe in adults and adolescents

CDC Updated Guidelines nPEP <https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf>

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What Testing Is Needed?

Test	Baseline	4-6 Weeks	3 Months	6 Months
HIV Ag/Ab	X	X	X	X
Hepatitis B	X	X	-	X
Hepatitis C	X	X	-	X
Syphilis	X	X	-	X
Gonorrhea	X	X	-	-
Chlamydia	X	X	-	-
Pregnancy	X	X	-	-
Renal Function	X			

CDC Updated Guidelines nPEP <https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf>

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How Effective Is nPEP?

- Not well studied (no randomized controlled trials)
 - 31.3 / 1000 persons with HIV infection (MSM) after nPEP (ongoing risk behavior in most)
- 81% odds reduction occupational (oPEP) with zidovudine

CDC Updated Guidelines nPEP <https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf>

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nPEP Regimen

- CrCl > 60
Tenofovir disoproxil fumarate 300mg + emtricitabine 200mg daily (Truvada®)
Plus
Dolutegravir (Tivicay) 50mg daily (recommended)
OR
Raltegravir (Isentress) 400mg daily

CDC Updated Guidelines nPEP <https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf>

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nPEP Regimen

- CrCl < 60:
Zidovudine (AZT)
AND
Lamivudine (Epivir)
AND
Dolutegravir (Tivicay) 50mg daily
OR
Raltegravir (Isentress) 400mg daily

CDC Updated Guidelines nPEP <https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf>

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Is PrEP covered by insurance?

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Is PrEP Covered By Insurance?

- PrEP
 - Covered by many health insurance plans
 - Copay assistance programs available
- Truvada for PrEP Medication Assistance Program:
 - Provides co-pay assist for medical care visits
 - Free condoms to patients on request
 - Access to free HIV testing
- <https://start.Truvada.com>

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Other PrEP Resources

- National Clinicians Consultation Center: PrEP line **1-855 HIV-PREP**
- The Gilead Advancing Access Program (uninsured and underinsured): **www.gileadcopay.com**

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How Should PreEP Visits Be Coded?

- PrEP ICD- billing code options:
 - Z20.6: Contact with and (suspected) exposure to HIV
 - Z20.2: Contact with and (suspected) exposure to infection with a predominantly sexual mode of transmission
 - Z77.21: Contact with and (suspected) exposure to potentially hazardous body fluids

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Practice Recommendations

- Your patient history should include screening for risk factors for HIV acquisition (C)
- Before initiating PrEP, your patient should have resulted HIV test within 1 week, and recent renal function and Hepatitis B tests (A)
- You should see patients on PrEP at least every 3 months to monitor side effects, draw labs, and check adherence (C)
- Consider a 28 day regimen of nPEP in patients with high risk exposure to a potential HIV source, which is safe in adults and adolescents (A)

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Questions



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Contact Information

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Articles and Resources Cited

Anderson PL, et al. "Vital Signs: Estimated Percentages and Numbers of Adults with Indications for Preexposure Prophylaxis to Prevent HIV Acquisition—United States, 2015." *MMWR*. 2015; 64: 1291-1295.

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