



NEW YORK STATE DEPARTMENT
OF HEALTH AIDS INSTITUTE

HIV Pre-Exposure Prophylaxis (PrEP)

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Objectives

- Discuss the NYS and CDC Guidelines for Pre-Exposure Prophylaxis (PrEP)
- Describe selection of candidates for PrEP
- Discuss the management of the patient on PrEP
- Discuss PrEP therapy and side effects
- Discuss the challenges associated with PrEP
- Discuss follow-up care including labs, PrEP, and counseling

Let's Talk about PrEP

3,000 New Yorkers are diagnosed with HIV every year

Governor Cuomo's "**End the Epidemic in NYS**" plan: to reduce the incidence rate to 750 new cases by 2020

This calls for a statewide initiative of ALL providers

We need you to get comfortable offering, prescribing, and managing PrEP

PrEP → a pill taken every day to prevent HIV infection



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How does PrEP Work?

Antiretroviral nucleoside analog HIV-1 reverse transcriptase inhibitor

TWO antiretroviral drugs that together inhibit the virus from replicating into new virus as it enters the body

Tenofovir disoproxil fumarate 300 mg + Emtricitabine 200 mg = TRUVADA
(1 pill EVERYDAY)



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Potential Candidates



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Who is a Candidate for PrEP?

Clinicians should discuss PrEP with the following non-HIV-infected individuals who have substantial and ongoing risk:

Men who have sex with men (MSM) who engage in unprotected anal intercourse

Individuals who are in a **serodiscordant sexual relationship** with a known HIV-infected partner

Male-to-female and female-to male **transgender individuals** engaging in high-risk sexual behaviors

Individuals engaging in **transactional sex**, such as sex for money, drugs, or housing

Injection drug users who report any of the following behaviors: sharing injection equipment (including to inject hormones among transgender individuals), injecting one or more times per day, injecting cocaine or methamphetamine, engaging in high-risk sexual behaviors

Individuals who use **stimulant drugs associated with high-risk behaviors**, such as methamphetamine

Individuals diagnosed with at least one anogenital **sexually transmitted infection** in the last year

Individuals who have been prescribed [non-occupational post-exposure prophylaxis](#) (nPEP) who demonstrate continued high-risk behavior or have used multiple courses of nPEP

Taking a Sexual History



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Take a sexual history from ALL patients:

5 P's of Sexual Health:

- **Partners**
 - Number and gender of partners over a given time (ex: last 12 months)
- **Practices**
 - Types of sexual practices→ oral, vaginal, anal
- **Protection from STIs**
 - Use of condoms or other methods
- **Past History of STIs**
 - Established risk of repeat infections (STI=HIV, herpes, gonorrhea, chlamydia, syphilis, HPV, trichomoniasis)? Last HIV test?
- **Prevention of Pregnancy**
 - Desire of pregnancy and use of contraceptive methods

Best practices for obtaining a sexual history

Ensure a safe patient environment

Assure confidentiality

Be non-judgemental

Be sensitive and matter-of-fact

Avoid assumptions

Take a sexual history from ALL Patients!!



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Prescription and Side Effects



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How to prescribe PrEP

PrEP should not be offered as a sole intervention for HIV prevention.

PrEP should only be prescribed **as part of a comprehensive prevention plan.**

PrEP may **help protect the HIV seronegative partner in a serodiscordant relationship during attempts to conceive.**

Only prescribe to patients who are **documented HIV negative** and **willing to adhere** to daily treatment

**Tenofovir disoproxil fumarate 300 mg + Emtricitabine 200 mg =
TRUVADA (1 tab PO daily)**

Side Effects

Common side effects:

Headache

Abdominal pain

Weight loss

Possible Adverse Events:

Kidney strain

Bone mineral density loss

Contraindications



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Contraindications to PrEP

Medical Contraindications:

Documented HIV infection

Drug-resistant HIV has been identified in patients with undetected HIV who subsequently received TDF/FTC for PrEP

Creatinine clearance <60 mL/min

Lack of readiness to adhere to a daily PrEP regimen is also a contraindication.

Efficacy of PrEP is dependent on adherence to ensure that plasma drug levels reach a protective level.



Assessment Checklist and Pre-Labs



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Pre-Prescription PrEP: Assessment Checklist



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Symptoms of Acute HIV Infection: Febrile, “flu”-, or “mono”-like illness in last 6 weeks

Medication List: Evaluate for potential drug-drug interactions

Substance Use and Mental Health Screening

Knowledge about PrEP

Readiness and Willingness to Adhere to PrEP: Potential barriers to daily adherence

Primary Care: Does the patient have a primary care provider? If not, provide referral.

Partner Information: Determine whether partners are known to be HIV-infected

For patients with an HIV-infected partner, ask: Is partner(s) receiving anti-retroviral therapy (ART)? And Is a resistance profile available?

Domestic Violence Screening

For Women: reproductive plans

Housing Status: Housing status and contact information should be closely monitored for patients with unstable living situations

Means to Pay for PrEP: Does the patient have insurance? If not, assess eligibility for Medicaid and refer to case worker for assistance with obtaining insurance

Before prescribing PrEP: Lab Tests

Baseline HIV Test

Obtain 4th generation (recommended) or 3rd generation (alternative) rapid HIV test (list of 3rd and 4th generation tests is available [here](#))

Perform nucleic acid amplification test (NAAT, viral load) for HIV for:

Patients with symptoms of [acute infection](#)

Patients whose antibody test is negative but who have reported unprotected sex with an HIV-infected partner in the last month

Drug-resistant HIV has been found in patients with undiagnosed HIV who were using TDF/FTC as PrEP.

Basic Metabolic Panel

Creatinine Clearance

Do NOT prescribe if CrCl <60



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Before prescribing PrEP: Lab Tests

Urinalysis

Hepatitis A, B, C

Vaccinate if needed

Sexually Transmitted Infection screening

3-point "NAAT" (genital, rectal, pharyngeal) for Gonorrhea/Chlamydia

Rapid Plasma Reagin/RPR for Syphilis

Pregnancy Test

Follow-up Schedule



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Schedule for Appointments and Tests



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Initial visit: Provide PrEP for 30 days (no refills!)

Follow up in 2 weeks to assess side effects (in person or by phone)

One month visit: Assess patient adherence, tolerance, commitment. Discuss risk reduction and provide condoms.

Give a prescription for 60 days (no refills!)

Three months: HIV testing, creatinine clearance, pregnancy test.

Ask about STI symptoms. Discuss risk reduction and provide condoms.

Confirm negative result before giving refill. Prescribe for 90 days if HIV negative and adherent.

6-month visit: HIV test, pregnancy test, STI screening tests. Discuss risk reduction and provide condoms.

Prescribe for 90 days if HIV negative and adherent.

9-month visit: HIV test, pregnancy test, STI screening tests. Creatinine clearance. Discuss risk reduction and provide condoms.

Prescribe for 90 days if HIV negative and adherent.

12 month visit: HIV test, pregnancy test, STI screening tests, urinalysis, HCV serology for MSM, IDUs and those with multiple partners. Discuss risk reduction and provide condoms.

Click for [PrEP Management Flowchart](#) of tests and visits

HIV Resistance and Acute HIV Symptoms



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Multidrug Resistant Strain of HIV

Resistance to PrEP is very rare ...but does exist

2 reported cases:

Toronto male (Feb 2016)

NYC male (Oct 2016)

Both adherent to PrEP but acquired a resistant strain of HIV



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Remember to Report

State law requires providers to report new cases of HIV within 14 days of diagnosis by calling: **NYSDOH (518) 474-4284**

Get familiar with signs and symptoms of acute HIV infection!!

Order an HIV test every 3 months in your PrEP patients



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Signs and Symptoms of Acute HIV Infection

Suspect in a patient:

Who has a negative mono test

Who goes to the doctor for the 1st time

Can appear very similar to the FLU or “mono”

<u>Acute or Early HIV</u>	<u>Flu or Common Cold</u>
Fever (lasting 6 weeks)	Fever
Sore Throat	Sore Throat
Swollen glands	Runny Nose
Rash	Cough
	Sneezing

Billing And Financial Aid



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How to bill for PrEP services

Most private insurance covers PrEP medication and services

https://www.health.ny.gov/diseases/aids/general/prep/docs/payment_options.pdf

There are no official billing codes for PrEP

Medicaid

Requires preauthorization

Pre-authorization worksheet:

https://newyork.fhsc.com/downloads/providers/NYRx_CDRP_PA_Worksheet_Prescribers_Truvadada.docx

Standard prior authorization form:

https://newyork.fhsc.com/downloads/providers/nyrx_pdp_pa_fax_standardized.pdf

Pre-Exposure Prophylaxis Assistance Program (PrEP-AP)

Provider must sign packet (Practitioner Specialty Provider Agreement) and send in mail

Enrolled providers will be reimbursed

Financial Help for Patients on PrEP

PrEP Assistance Program (PrEP-AP)

Covers doctor visits and lab testing

PrEP-AP: (800)-542-2437 (Hotline)

www.health.ny.gov/diseases/aids/general/resources/adap

Gilead Co-pay Coupon

(877)-505-6986

www.gileadcopay.com

Patients must have insurance but not Medicare or Medicaid

Covers up to \$300/month in prescription co-pays

Gilead Truvada for PrEP Medication Assistance Program

(855)-330-5479

www.start.truvada.com/individual

Covers prescription costs



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Financial Help for Patients on PrEP (cont)

Patient Advocate Foundation Co-Pay Relief Program

Provides financial assistance to financially and medically qualified patients for co-payments, co-insurance, and deductibles

(866) 512-3861

www.copays.org

Financial resources

Partnership for Prescription Assistance (PPA) Program

(888) 477-2669

www.pparx.org

Designed to help uninsured Americans get the prescription medicines they need at no or low cost

Gilead Advancing Access

(800) 226-2056

www.gileadadvancingaccess.com

Matches patients to an assistance program for Gilead medications that best meets their financial needs based on particular circumstances, insurance, and the eligibility criteria for the programs.

Resources for Providers



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Resources for Providers

Interactive Clinical Guideline-Based Simulations - CEInema

<http://m.ceitraining.org/simulation.cfm>

Clinical Education Initiative (www.ceitraining.org)

<https://ceitraining.org/resources/prep>

Free CME/CNE/CPE credits

Clinician Inquiry line **1-866-637-2342**

New York State Department of Health AIDS Institute

<https://www.health.ny.gov/diseases/aids/general/prep/index.htm#prep>

HIV Clinical Resources

www.hivguidelines.org



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Clinical Education Initiative

Clinical Education Initiative (CEI) is a project supported by the New York State Department of Health (NYSDOH) AIDS Institute (AI) to:

- provide progressive HIV, HCV and STD live and online continuing medical education to clinicians
- expand the base of providers able to diagnose and care for HIV, HCV and STD patients, and therefore to improve patients' health outcomes.
- disseminate AIDS Institute clinical guidelines

CEI offers live (in person) trainings, webinars, preceptorships, TA, online trainings, interactive case simulations.

Our trainings offer free CME/CNE/CPE credits.

All these resources are delivered through various platforms: live (in person) trainings, website (www.ceitraining.org), Android and iOS apps, social media and CEI Newsletters.



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CEI ECHO Project

About CEI ECHO

Clinical Education Initiative (CEI) offers an exciting new "telementoring" program for NYS providers of STD and HIV clinical care.

Using the [ECHO™](#) model, CEI ECHO Sessions will provide a regular opportunity to discuss cases from your practice with experts in STD and HIV prevention, diagnosis and treatment. Each session will feature a short didactic presentation.

How does it work?

Through monthly teleconferences using Zoom, ECHO links expert specialist teams at an academic "hub" with clinicians in local practice settings, known as "spokes" in the model.

Together, they develop a learning community where the spokes receive mentoring and feedback from specialists.



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PrEP Voluntary Prescriber Directory



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NYSDOH PrEP Voluntary Provider Directory

Please sign up to become available for patients who need PrEP in your area

NYSDOH PrEP/PEP Provider Directory info page:

https://www.health.ny.gov/diseases/aids/general/prep/provider_directory.htm

Directory sign-up:

<https://www.surveymonkey.com/s/S329ZK5>



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Thank you for your time and commitment

Please do not hesitate to access the resources available for providers:

NYSDOH AIDS Institute:

<https://www.health.ny.gov/diseases/aids/general/prep/index.htm>

CEI Clinician Inquiry line: 1-866-637-2342

www.ceitraining.org

<https://ceitraining.org/resources/prep/>

www.hivguidelines.org



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Questions?