



Webcast 1.3

US Public Health Service Clinical Practice Guidelines for PrEP

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Federal PrEP Guidelines

- Released on May 14, 2014 by the US Public Health Service
- Developed by a federal inter-agency working group led by the Centers for Disease Control and Prevention (CDC), with input from providers, HIV patients, partners, and affected communities
- Recommend that PrEP be considered for people who are HIV-negative and at substantial risk for HIV

Federal PrEP Guidelines

- Provide clear criteria for determining a person's HIV risk and indications for PrEP use.
- Require that patients receive HIV testing to confirm negative status before starting PrEP.
- Underscore importance of counseling about adherence and HIV risk reduction, including encouraging condom use for additional protection.
- Recommend regular monitoring of HIV infection status, side effects, adherence, and sexual or injection risk behaviors.
- Include a providers' supplement with additional materials and tools for use when prescribing PrEP.

Summary of Guidance for PrEP Use

	Men Who Have Sex With Men	Heterosexual Women and Men	Injection Drug Users
Detecting substantial risk of acquiring HIV infection:	<ul style="list-style-type: none"> Sexual partner with HIV Recent bacterial STD High number of sex partners History of inconsistent or no condom use Commercial sex work 	<ul style="list-style-type: none"> Sexual partner with HIV Recent bacterial STD High number of sex partners History of inconsistent or no condom use Commercial sex work Lives in high-prevalence area or network 	<ul style="list-style-type: none"> HIV-positive injecting partner Sharing injection equipment Recent drug treatment (but currently injecting)
Clinically eligible:	<ul style="list-style-type: none"> Documented negative HIV test before prescribing PrEP No signs/symptoms of acute HIV infection Normal renal function, no contraindicated medications Documented hepatitis B virus infection and vaccination status 		
Prescription	Daily, continuing, oral doses of TDF/FTC (Truvada), ≤90 day supply		
Other services:	<ul style="list-style-type: none"> Follow-up visits at least every 3 months to provide: HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STD symptom assessment At 3 months and every 6 months after, assess renal function Every 6 months test for bacterial STDs 		
	<ul style="list-style-type: none"> Do oral/rectal STD testing 	<ul style="list-style-type: none"> Assess pregnancy intent Pregnancy test every 3 months 	<ul style="list-style-type: none"> Access to clean needles/syringes and drug treatment services

Source: US Public Health Service. Preexposure prophylaxis for the prevention of HIV infection in the United States —2014: a clinical practice guideline.

Recommended Ratings

Quality of Evidence	Strength of Recommendation
I. One or more well executed, randomized controlled trials with clinical outcomes, validated laboratory endpoints or both	A. Strong recommendation
II. One or more well executed nonrandomized trials or observational cohort studies with clinical outcomes	B. Moderate recommendation
III. Expert opinion	C. Optional recommendation

Key Messages of the Guidelines

US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES - 2014

A CLINICAL PRACTICE GUIDELINE



Daily oral PrEP is recommended as one prevention option for:

- Sexually active adult men who have sex with other men at substantial risk for HIV. (IA)
- Adult heterosexually active men and women at substantial risk for HIV. (IA)
- Adult injection drug users at substantial risk for HIV. (IA)
- And should be discussed with heterosexually active partners of persons living with HIV in relation to conception and pregnancy. (IIB)

Indications for PrEP in MSM

Adult man:

- Without acute or established HIV infection
- Any male sex partners in past 6 months
- Not in a monogamous partnership with a recently tested, HIV-negative man

AND at least one of the following:

- Any anal sex without condoms (receptive or insertive) in past 6 months
- Any STI diagnosed or reported in past 6 months
- Is in an ongoing sexual relationship with an HIV-positive male partner

Indications for PrEP in Heterosexual Men and Women

Adult person:

- Without acute or established HIV infection
- Any sex with opposite sex partners in past 6 months
- Not in a monogamous partnership with a recently tested, HIV-negative partner

AND at least one of the following:

- Is a man who has sex with both women and men (behaviorally bisexual) [also evaluate indications for PrEP use by MSM criteria]
- Infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are known to be at substantial risk of HIV infection (IDU or bisexual male partner)
- Is in an ongoing sexual relationship with an HIV-positive partner

Indications for PrEP in IDU

Adult person:

- Without acute or established HIV infection
- Any injection of drugs not prescribed by a clinician in past 6 months

AND at least one of the following:

- Any sharing of injection or drug preparation equipment in past 6 months
- Been in a methadone, buprenorphine, or suboxone treatment program in past 6 months
- Risk of sexual acquisition (also evaluate by MSM and Heterosexual criteria)

PrEP in Adolescents

- The data on efficacy and safety in adolescents are insufficient.
- The risks and benefits of PrEP for adolescents should be weighed carefully in the context of local laws and regulations about autonomy in health care decision-making by minors. (IIIB)

Prescribing PrEP

Rule out chronic and acute HIV infection

- Query patient about recent exposure
- Ask about symptoms of acute or primary HIV infection
- Perform HIV screening test
- If acute infection is possible:
 - Screen using a highly sensitive test: 4th generation or viral load test
 - Or postpone PrEP until repeat HIV screening completed in one month

Prescribing PrEP

Other laboratory tests

- Renal function: PrEP should not be prescribed to persons with a creatinine clearance of < 60 ml/min
- Hepatitis B and C
 - As PrEP may have partial efficacy against hepatitis, it is important to document infection
 - Vaccination for hepatitis A and B is recommended for MSM
- STI screening in all appropriate anatomic sites: gonorrhea, chlamydia, syphilis

Prescribing PrEP

Prescribe up to 3 months worth of PrEP

- The only regimen approved by the FDA and recommended for PrEP with all populations specified in the guideline is the co-formulated tenofovir 300 mg/entircitibine 200 mg (Truvada). (IA)
- Tenofovir alone has shown efficacy and safety in heterosexuals and IDU (but not MSM) and can be considered for these populations. (IC)
- The use of other medications in place or in addition to TDF/FTC or TDF alone is not recommended. (IIIA)
- Prescribing PrEP for coitally-timed or other noncontinuous daily use is not recommended. (IIIA)

Reinforcing Adherence

Adherence counseling

- Establish trust and bidirectional communication
- Provide simple explanations and education
 - Dose and side effects
 - Importance of adherence
 - Symptoms of acute infection

Reinforcing Adherence

Adherence counseling (cont'd)

- Support adherence
 - Dosing schedule tailored to daily routine
 - Reminders
 - Identify barriers to adherence
- Monitor medication adherence in a nonjudgmental manner
 - Reinforce success
 - Identify and manage side effects

Reinforcing Safe Behaviors

Behavioral risk-reduction counseling

- Establish trust and bidirectional communication
- Provide feedback on HIV risk factors identified during sexual and substance use history taking
 - Barriers to and facilitators of consistent condom use
 - Barriers to and facilitators of reducing substance use

Reinforcing Safe Behaviors

Behavioral risk-reduction counseling (cont'd)

- Support risk reduction efforts
 - Identify acceptable incremental steps to risk reduction
 - Identify and address barriers to risk reduction plans
- Monitor behavioral adherence in a nonjudgmental manner
 - Reinforce success
 - If not successful, assist in modifying risk reduction plans

Follow-up Visits

Every 3 months

- Repeat HIV testing and assess for signs/symptoms of acute infection to document that patients are still HIV-negative. (IA)
- Repeat pregnancy testing for women who may become pregnant.
- Provide a prescription or refill authorization of daily TDF/FTC for no more than 90 days (until the next HIV test).
- Assess side effects, adherence, and HIV risk behaviors.
- Provide support for medication adherence and risk-reduction behaviors.
- Respond to new questions and provide any new information about PrEP use.

Follow-up Visits

Every 6 months

- Monitor creatinine clearance. (IIIA)
- Conduct STI testing recommended for sexually active adolescents and adults (i.e. syphilis, gonorrhea, chlamydia).

Follow-up Visits

Discontinuing PrEP

- Document HIV status
- Understand reason for discontinuing PrEP
- Counsel based on recent adherence and risk behaviors

Clinical Provider's Supplement

US PUBLIC HEALTH SERVICE

PREEXPOSURE PROPHYLAXIS
FOR THE PREVENTION OF HIV
INFECTION IN THE UNITED
STATES – 2014

CLINICAL PROVIDERS' SUPPLEMENT



Contents

Introduction	3
Section 1	Patient/Provider Checklist.....	4
Section 2	Patient Information Sheet – PrEP	6
Section 3	Patient Information Sheet – Truvada.....	9
Section 4	Patient Information Sheet – Acute HIV Infection and PrEP	12
Section 5	Provider Information Sheet – PrEP During Conception, Pregnancy, and Breastfeeding.....	14
Section 6	HIV Incidence Risk Index for Men Who Have Sex With Men	20
Section 7	Supplemental Counseling Information—Medication Adherence	22
Section 8	Supplemental Counseling Information—HIV Risk Reduction.....	27
Section 9	PrEP-related ICD, CPT and LOINC Codes	29
Section 10	Potential PrEP Practice Quality Measures	36
Section 11	Methods for Developing the PrEP Clinical Practice Guideline	37
References	40

NACCHO's Webcast Series on PrEP and Local Health Departments

Module 1

PrEP for HIV Prevention: An Introduction

Beyond the Basics: The Science of PrEP

US Public Health Service Clinical Practice Guidelines for PrEP

Module 2

Who Might Benefit from PrEP: Population-level Risk Assessments

Who Might Benefit from PrEP: Individual-level Risk Assessments

Module 3

Increasing PrEP Awareness and Knowledge in Your Jurisdiction

Incorporating PrEP into Comprehensive HIV Prevention Programs