Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

Guidance for the use of pre-exposure prophylaxis (PrEP) to prevent HIV transmission.

Bibliographic Source(s)

New York State Department of Health. Guidance for the use of pre-exposure prophylaxis (PrEP) to prevent HIV transmission. New York (NY): New York State Department of Health; 2014 Jan. 23 p. [19 references]

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Key Principles for Prescribing Pre-exposure Prophylaxis (PrEP)

- PrEP should not be offered as a sole intervention for human immunodeficiency virus (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.
- PrEP is indicated for individuals who have a documented negative HIV test result and are at ongoing high risk for HIV infection. A negative HIV test result needs to be confirmed as close to initiation of PrEP as possible, ideally on the same day the prescription is given. Clinicians should wait to prescribe PrEP until confirmation of a negative test result is available.
- Efficacy of PrEP is dependent on adherence. PrEP should only be prescribed to those who are able to adhere to the regimen and express a willingness to do so.
- Although consistent condom use is a critical part of a prevention plan, lack of use of barrier protection is not a contraindication to PrEP.
- PrEP is contraindicated in individuals with documented HIV infection or creatinine clearance <60 mL/min, and in those who are not ready to adhere to daily PrEP.
- The first prescription of PrEP (Truvada 1 tablet PO daily) should only be for 30 days to allow for a follow-up visit to assess adherence, tolerance, and commitment. At the 30-day visit, a prescription for 60 days may be given; the patient should then return for 3-month HIV testing and other assessments. After that visit, prescriptions can be given for 90 days, provided that the patient is adherent.
- Patients receiving PrEP require regular visits, at least every 3 months, to monitor HIV status, adherence, and side effects. Follow-up and monitoring of patients receiving PrEP also includes prevention services that are part of a comprehensive prevention plan, such as risk-reduction counseling, access to condoms, sexually transmitted infection (STI) screening, and mental health and substance use screening, when indicated.

- Whenever patients present with symptoms of acute HIV infection, an HIV serologic screening test should be used in conjunction with a plasma HIV ribonucleic acid (RNA) assay.
- Discontinue PrEP immediately for patients who receive a positive HIV test result. Obtain a genotypic assay, and refer and link to HIV care.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Human immunodeficiency virus (HIV) infection

Guideline Category

Counseling

Evaluation

Management

Prevention

Treatment

Clinical Specialty

Allergy and Immunology

Emergency Medicine

Family Practice

Infectious Diseases

Internal Medicine

Obstetrics and Gynecology

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Nurses

Physician Assistants

Physicians

Public Health Departments

Social Workers

Guideline Objective(s)

To provide guidance for delivery of a human immunodeficiency virus (HIV) prevention program that includes the use of pre-exposure prophylaxis (PrEP)

Target Population

Patients at risk for infection such as men having sex with men (MSM), serodiscordant couples, and injection drug users

Interventions and Practices Considered

1. Pre-exposure prophylaxis (PrEP) as part of a comprehensive prevention plan
2. Monitoring human immunodeficiency virus (HIV) status, adherence, and side effects, including HIV serologic screening test in conjunction with a plasma HIV ribonucleic acid (RNA) assay
3. Discontinuation of PrEP in patients with positive test results

Major Outcomes Considered

- Human immunodeficiency virus (HIV) transmission
- HIV infection

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The National Library of Medicine, PubMed Central, Cochrane library, and Medline were the databases searched. In addition, the interim guidance documents issued from the Centers for Disease Control and Prevention were searched. The date range (begin and end date) of the literature search(es) was 2005 to 2013. The inclusion criteria used in the searches were: non-HIV-infected, clinical trials for use of PrEP. The exclusion criteria used in the search were: ARV-infected, adolescents/children. The specific search terms used were: pre-exposure prophylaxis; ARV post exposure prophylaxis for MSM/heterosexual men/women; adherence; tenofovir + emtricitabine (TDF/FTC, Truvada); HIV incidence among MSM; mother-to-child transmission; serodiscordant couples.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus (Committee)

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

AIDS Institute clinical guidelines are developed by distinguished committees of clinicians and others with extensive experience providing care to people with HIV infection. Committees* meet regularly to assess current recommendations and to write and update guidelines in accordance with newly emerging clinical and research developments.

The Committees* rely on evidence to the extent possible in formulating recommendations. When data from randomized clinical trials are not available, Committees rely on developing guidelines based on consensus, balancing the use of new information with sound clinical judgment that results in recommendations that are in the best interest of patients.

*Current committees include:

- Medical Care Criteria Committee
- Committee for the Care of Children and Adolescents with HIV Infection
- Dental Standards of Care Committee
- Mental Health Guidelines Committee
- Committee for the Care of Women with HIV Infection
- Committee for the Care of Substance Users with HIV Infection
- Physician's Prevention Advisory Committee
- Pharmacy Advisory Committee

In September 2012, the New York State Department of Health convened a PrEP Advisory Panel to develop clinical guidance on the use of PrEP. The Panel consisted of primary care providers caring for high-risk populations, clinicians experienced in the treatment of HIV, obstetricians, adolescent care providers, pharmacists, program administrators, social workers, policy makers, representatives from the New York City Department of Health and Mental Hygiene, and consumer representatives.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

All guidelines developed by the Committee are externally peer reviewed by at least two experts in that particular area of patient care, which ensures depth and quality of the guidelines.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Effective use of pre-exposure prophylaxis (PrEP) to prevent human immunodeficiency virus (HIV) transmission
- Decreased risk of acquisition of acute HIV infection during pregnancy, which is a significant risk factor for mother-to-child HIV transmission

Potential Harms

- Discontinuation of tenofovir/emtricitabine (TDF/FTC) requires close monitoring in patients with chronic hepatitis B infection because of the concern for rebound viremia.
- If a woman is pregnant when starting pre-exposure prophylaxis (PrEP) or becomes pregnant while on PrEP, discuss the known risks and benefits of taking TDF/FTC during pregnancy (see Table 5 in the original guideline document).
- PrEP has not been studied in individuals younger than 18 years of age.

Side Effects

- The most common side effects of TDF/FTC are headache, abdominal pain, and weight loss; however, these side effects usually resolve or improve after the first month. Two weeks after initiation of PrEP, clinicians should follow up either in person or by phone to assess side effects. Standard measures, such as antidiarrheal agents, anti-gas medications, and antiemetics, should be used to alleviate gastrointestinal side effects as needed.
- Use of TDF/FTC in human immunodeficiency virus (HIV)-infected patients has shown that side effects, such as renal impairment or bone density loss, can occur. Although uncommon, regular laboratory monitoring for these parameters is necessary (see Table 8 in the original guideline document). If a decrease in serum creatinine and calculated creatinine clearance is observed, potential causes should be evaluated.

Contraindications

Contraindications

Contraindications to Pre-exposure Prophylaxis (PrEP)

Medical Contraindications

- Documented human immunodeficiency virus (HIV) infection
  - Drug-resistant HIV has been identified in patients with undetected HIV who subsequently received tenofovir + emtricitabine (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.

Qualifying Statements

Qualifying Statements

When formulating guidelines for a disease as complex and fluid as human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS), it is impossible to anticipate every scenario. It is expected that in specific situations, there will be valid exceptions to the approaches offered in these guidelines and sound reason to deviate from the recommendations provided within.

Implementation of the Guideline

Description of Implementation Strategy

The AIDS Institute's Office of the Medical Director directly oversees the development, publication, dissemination and implementation of clinical practice guidelines, in collaboration with The Johns Hopkins University, Division of Infectious Diseases. These guidelines address the medical management of adults, adolescents and children with human immunodeficiency virus (HIV) infection; primary and secondary prevention in medical settings; and include informational brochures for care providers and the public.

Guidelines Dissemination

Guidelines are disseminated to clinicians, support service providers, and consumers through mass mailings and numerous AIDS Institute-sponsored educational programs. Distribution methods include the HIV Clinical Resource website, the Clinical Education Initiative (CEI), the AIDS Educational Training Centers (AETC), and the HIV/AIDS Materials Initiative. Printed copies of clinical guidelines are available for order from the New York State Department of Health (NYSDOH) Distribution Center.

Guidelines Implementation

The HIV Clinical Guidelines Program works with other programs in the AIDS Institute to promote adoption of guidelines. Clinicians, for example, are targeted through the CEI and the AETC. The CEI provides tailored educational programming on site for health care providers on important topics in HIV care, including those addressed by the HIV Clinical Guidelines Program. The AETC provides conferences, grand rounds and other programs that cover topics contained in AIDS Institute guidelines.

Support service providers are targeted through the HIV Education and Training initiative which provides training on important HIV topics to non-physician health and human services providers. Education is carried out across the State as well as through video conferencing and audio conferencing.

The HIV Clinical Guidelines Program also works in a coordinated manner with the HIV Quality of Care Program to promote implementation of HIV guidelines in New York State. By developing quality indicators based on the guidelines, the AIDS Institute has created a mechanism for measurement of performance that allows providers and consumers to know to what extent specific guidelines have been implemented.

Finally, best practices booklets are developed through the HIV Clinical Guidelines Program. These contain practical solutions to common problems related to access, delivery or coordination of care, in an effort to ensure that HIV guidelines are implemented and that patients receive the highest level of HIV care possible.

Implementation Tools

Chart Documentation/Checklists/Forms

Patient Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2014 Jan

Guideline Developer(s)

New York State Department of Health - State/Local Government Agency [U.S.]

Source(s) of Funding

New York State Department of Health

Guideline Committee

New York State Department of Health PrEP Advisory Panel

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Financial Disclosures/Conflicts of Interest

Prior to participation, each panel member submitted a financial disclosure form in accordance with the program's conflict of interest policy. Two panel members reported potential conflicts with Gilead, manufacturer of Truvada. JB-M, Speaker's Bureau; AU, Speaker's Bureau.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the New York State Department of Health AIDS Institute Web site .

Availability of Companion Documents

Pre-prescription checklists for assessment and patient education are available in the original guideline document .

Patient Resources

The following are available:

- Pre-exposure prophylaxis (PrEP): questions and answers. Electronic copies: Available from the New York State Department of Health (NYSDOH) Web site .
- Pre-exposure prophylaxis (PrEP) to prevent HIV infection. HIV Q&A fact sheet. 2013 Jan. Electronic copies: Available from the NYSDOH AIDS Institute Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

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