GUIDELINES FOR PRE-EXPOSURE PROPHYLAXIS FOR HUMAN IMMUNODEFICIENCY VIRUS (HIV) WITHIN IHS, TRIBAL AND URBAN INDIAN HEALTHCARE FACILITIES

This template is a sample policy for HIV Pre Exposure Prophylaxis (PrEP). This is a template, and as such it is not comprehensive and does not mandate any clinical activities. It does provide a sample policy for I/T/U facilities to provide PrEP services at the primary care level, and should be adapted as needed to reflect local conditions and priorities. A PrEP policy can be instrumental for clinical staff to understand PrEP eligibility, patient needs, clinical algorithms, and best practices. PrEP can be highly effective in preventing new HIV infections and ongoing transmission to the community. For further questions or support, contact Dr. Jonathan Iralu, Chief Clinical Consultant, Infectious Disease, jonathan.iralu@ihs.gov

PURPOSE

To expand access to Pre-Exposure Prophylaxis for the prevention of HIV infection.

BACKGROUND

Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome (HIV/AIDS) is a complex and growing problem in the United States, affecting an estimated 1.2 million persons, with approximately 50,000 new infections diagnosed each year. Although American Indian/Alaska Native (AI/AN) populations comprise only about one percent of national HIV/AIDS infections, when population size is considered, AI/AN populations rank 3rd in HIV/AIDS incidence after African Americans and Hispanics. (1)

In addition, sexually transmitted infections (STIs) such as chlamydia and syphilis occur at higher incidence rates among AI/AN than the United States average. STIs, specifically syphilis, have been shown to increase the risk of HIV transmission. (2)

Pre-exposure prophylaxis, or PrEP, has the potential to decrease the burden of HIV among patients at high risk of infection. A proportion of men who have sex with men (MSM), Persons who inject drugs (PWID), and heterosexual patients will be eligible for PrEP. PrEP has been shown to decrease HIV infection by >90%. However, patients on PrEP must be adherent to daily medication, and require routine medical visits for HIV/STI screening and drug toxicity. (3)

PrEP is supported by four lines of evidence: anti-infective prophylaxis, prevention of mother-to-child transmission of HIV, Post-Exposure prophylaxis for HIV (PEP), and studies in animal models. In large scale human subject trials, PrEP has shown a reduction in HIV infection by approximately 50% overall, but upwards of 90% for highly adherent patients. (4)

PrEP patients must be checked prior to and during prophylaxis for the presence HIV infection; PrEP can lead to accelerated drug resistance if taken while HIV infected.

PrEP Recommendations

- Patient assessment for elevated risk of HIV generally falls into three main categories as per table 1. A sexual and risk history should be done for each potential PrEP patient (under additional resources). MSM is to include transgender women (male to female transgender individuals) who have sex with men

• MSM	• Heterosexual Women and Men	• People who Inject Drugs
• HIV-positive sexual partner • Recent bacterial STI • High number of sex partners • History of inconsistent or no condom use • Commercial sex work	• HIV-positive sexual partner • Recent bacterial STI • High number of sex partners • History of inconsistent or no condom use • Commercial sex work • In high-prevalence area or network	• HIV-positive injecting partner • Sharing injection equipment • Recent drug treatment (but currently injecting)

- Determine clinical eligibility, to include confirmation that the patient is not infected with HIV, HBV status or vaccination, HCV status, renal function (eCrCl must be $\geq$ 60 mL/min), and rule out acute HIV (no fever, fatigue, pharyngitis, cervical adenopathy, or skin rash in last 4 weeks, or rule out with HIV RNA/viral load test)
- STI screen should be done prior to PrEP, including syphilis, gonorrhea, and chlamydia, including pharyngeal and rectal GC/CT swabs, but must be done every 3-6 months after initiation of PrEP. (1) Patients can self-swab with proper instruction, see resources
- Patient counseling, to include importance of adherence and quarterly medical visits for HIV/STI screening and drug toxicity
- Rule out drug interactions
- Test females for pregnancy

Treatment

- Patients will be prescribed Truvada (TDF/FTC 300/200 mg) taken one pill daily with a 90 day supply.(1)

- Patients will be discontinued from PrEP if they have a confirmed HIV or HBV infection, renal function (CrCl) declines <50 mL/min or new proteinuria without other etiologic reason, patient nonadherent with PrEP or follow up appointments, Truvada intolerance or allergy, or HIV risk behavior no longer present.

VACCINATIONS

- Hepatitis B vaccination should be offered to all unvaccinated, uninfected persons being evaluated for PrEP.
- HPV vaccination is recommended for all women (including immunocompromised) between the ages of 9-26 regardless of prior sexual activity, HPV infection, or abnormal PAP results.
- HPV vaccination is recommended for males between the ages of 9-21 regardless of prior sexual activity or HPV infection.
- HPV vaccination is recommended for MSM through age 26.
- HPV4 or HPV9 vaccines are acceptable for men or women.

QUESTIONS AND RESOURCES

- This sample policy and protocol can be adapted for local use. These documents and accompanying information sheets can be found on the IHS STI Program website (under additional resources).
- Questions regarding HIV diagnosis, treatment, patient and partner follow-up, and reporting should be directed to the appropriate local tribal health department or to the respective state HIV program.
- CDC has guidance has guidance for PrEP for heterosexual adults, persons who inject drugs, and men who have sex with men (under additional resources).
- PrEPline consult for clinicians: 855-488-7737 11am-6pm Eastern, operated by University of California San Francisco (UCSF)

CONTACT INFORMATION FOR LOCAL HEALTH DEPARTMENT:

<<insert address for reporting>>

<<insert phone number>>

<<insert fax number>>

Additional Resources:

1. Guideline: CDC. Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United States: A Clinical Practice Guidleine. http://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf
2. Taking a sexual history https://www.ihs.gov/epi/documents/std/PerformingSexualRiskAssessment.pdf
3. STI/HIV Policy and Procedures https://www.ihs.gov/epi/index.cfm?module=epi_std_resources
4. Primer on PREP from CDC: www.cdc.gov/hiv/prep
5. PrEP hotline: http://nccc.ucsf.edu/2014/09/29/introducing-the-ccc-prepline
6. Smartphone reminder for patients adherence https://start.truvada.com/hcp/hiv-testing-reminders?scrollTop=.smarthPhoneLinks
7. Risk and evaluation mitigation strategies http://www.truvadapreprems.com/#
8. Information for patients https://start.truvada.com/

Addendum: Billing considerations

Truvada is on the IHS National Core Formulary (NCF) for Post-Exposure Prophylaxis of HIV. Use for PrEP is a facility-level decision.

The annual cost of once daily Truvada® and the associated visits/tests is estimated to be $13,000. As a result of FDA approval for the use of Truvada® as PrEP, many health insurers, will cover the cost. Prior authorization may be required; check with the insurer.

Gilead Sciences, the manufacturer of Truvada®, has established a patient assistance program to help people without health insurance or other coverage to obtain access to Truvada®. Information about eligibility for this program is available by calling 1-855-330-5479.

Citations

(1) https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/todaysepidemic-508.pdf

(2) http://www.cdc.gov/hiv/group/racialethnic/aian/

(3) http://www.cdc.gov/hiv/risk/prep/

(4) http://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf