

Indian Health Service

HIV Primary Care Guideline

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Background:

Clinical care of the patient with HIV infection is a rapidly changing field. Recent advances in the treatment of HIV make this infection a Primary Care condition treatable at any IHS facility. This document helps set down standards of care for People Living with HIV/AIDS (PLWHA) at Indian Health Service facilities. These standards are updated periodically.

The Primary Care Visit:

The initial primary care visit is perhaps the most important visit of all. The patient has just received intimidating and frightening news and is at a vulnerable point in life. It is the duty of the primary care provider to listen carefully to the patient's concerns, establish rapport and offer reassurance that care will be given in a compassionate, nonjudgmental, culturally appropriate manner. It is very important to treat the patient before you as a person and not a diagnosis. It is a good idea to spend most of the first visit in conversation to make sure that all of the patient's initial concerns are addressed.

History(ref 4):

In taking a history, it is important to establish when the patient was first diagnosed. A history of prior opportunistic infections, malignancies and the initial CD4 count and HIV viral load are helpful pieces of information. Obtaining the prior HIV antiretroviral therapy history is important if the patient is able to provide it. A psychiatric history including past diagnoses such as depression, anxiety, post-traumatic stress disorder and substance use disorder is important. The social history should be obtained including substance use (cigarettes, alcohol, drugs), sexual practices (including exposure sites, number of partners, and partners' HIV status). It is helpful to ask about social supports, employment, housing, and income at one of the early clinic visits. Completing a standard review of symptoms is imperative.

Physical Exam(ref 4):

A standard HIV physical exam should include the following special elements:

- Vital signs
- Eyes: Assess sclerae for icterus suggesting liver disease, irregular pupils suggesting ocular syphilis, and retinal exam for cotton wool spots (commonly seen with HIV) and for retinitis.
- Oropharynx: Assess the mucosa for thrush secondary to candida, the tongue for hairy leukoplakia (vertical striations on the lateral surface suggesting advanced stage 3 HIV disease), mucous patches and chancres suggesting syphilis and the gingiva for signs of gingivitis.
- Lymph nodes: assess all lymph node groups including cervical, axillary, epitrochlear and inguinal.

- Lungs: evaluate for signs of pneumonia and effusion
- Abdomen: assess for tenderness and hepato-splenomegaly
- Genital: Evaluate both females and males for warts, ulcers, discharge, etc
- Anal: evaluate for ulceration, mass and discharge
- Neurologic: Evaluate for signs of dementia, peripheral neuropathy and focal deficits suggesting a mass lesion or stroke.

Laboratory Evaluation (ref 3)

Patients followed in IHS facilities for HIV will have the following tests performed at baseline and during follow up visits as noted.

Test	Frequency	Comments
CD4 Count	At diagnosis, then at 12 weeks after starting meds. After that obtain CD4 every 3 months at first then every 6-12 months when viral load is undetectable and CD4 >200	Use one laboratory and methodology
HIV Viral Load	At diagnosis then at 4 and 12 weeks after starting meds. After that obtain an HIV viral load every 3 months at first then every 6 months after 2 years of viral suppression (HIV viral load < 200 copies/ml).	Use one laboratory and methodology
Genotypic antiretroviral Resistance Test	At diagnosis on all patients and subsequently only with failure of virologic control	Test prior to starting antiretroviral therapy on all patients
RPR	At diagnosis and yearly	LP if positive only if exam suggests ocular, otic or neurosyphilis
GC/Chlamydia	At diagnosis and yearly	Order Urine, Rectal & Pharyngeal testing based on sites of exposure
Quantiferon assay or PPD	At diagnosis and yearly	See treatment recommendation below for positive test response.
HBsAg, HBsAb, HCV Ab, Hep A total Ab	Once for all patients. Test MSM, transgender women and people who inject drugs (PWID) annually for Hepatitis B and C	Vaccinate for Hep A and B if serology is negative
Toxoplasma Ab	Once	Prophylaxis if CD4<100

CMV Ab	Once only if low risk (non MSM, non PWID)	
Varicella Ab	Once if no h/o Chickenpox or Shingles	Consider vaccination if negative and CD4 > 200
CXR	Once but only if symptomatic or PPD/QFT +	
CMP/CBC	Q 3-4 months or when CD4 and viral load are done	
Urinalysis	Obtain at baseline and annually	
Pregnancy	Obtain prior to starting antiretroviral therapy	
Cervical PAP smear	Q 6 months x 2 then yearly	
Anal pap smear	Annually in MSM and women (trans and cis gender) if there is a history of anal sex, abnormal cervical PAP or history of genital warts	Recommended test. Refer positives for high resolution anoscopy
Lipids	Baseline and annually	
Hgb A1c and fasting glucose	Baseline and annually	
G-6-PD level	once	
HLA B*5701 assay	Once for patient who will be placed on abacavir	Used to detect risk for abacavir hypersensitivity syndrome

Antiretroviral Therapy (ref 1)

Antiretroviral therapy for HIV is now on the Indian Health Service Core Formulary. The standard indication for antiretroviral therapy is now quite simple:

Treat all HIV positive patients regardless of CD4 Count.

The preferred single tablet regimen for most patients is **Tenofovir Alafenamide/Emtricitabine/Bictegravir (Biktarvy™)** one po daily if there are no resistance mutations to the three components noted on the initial genotypic antiretroviral resistance test (GART). This drug should be avoided in persons with a Creatinine Clearance less than 30. A second excellent regimen on the Core Formulary for patients intolerant of the first regimen is **Abacavir/Lamivudine/Dolutegravir (Triumeq™)** one PO daily. This single pill regimen requires pre-screening to make sure the patient is HLA B*5701 negative to avoid a potentially fatal hypersensitivity reaction to abacavir. The abacavir component in this pill has been linked in some studies to cardiovascular complications so this is not the first choice regimen for patients with established heart disease or high risk for heart disease. The integrase inhibitors in these two tablets, dolutegravir and biktgravir interact with antacids, rifamycins, anti-epileptics and

metformin. It is wise to use a drug interaction app before starting these antivirals or adding new medications.

Pregnant women during the first trimester and non-pregnant women with HIV considering becoming pregnant can be offered tenofovir disoproxil fumarate/emtricitabine (Truvada™) plus Raltegravir. During the second and third trimester raltegravir can be switched to dolutegravir for increased potency with a smaller pill burden. Tenofovir alafenamide and the boosting agent cobicistat are to be avoided in pregnancy. Dolutegravir is avoided during the first trimester as some studies suggest a link to neural tube defects. Bictegravir safety in early pregnancy is unknown so this drug is in general avoided.

Please consult an HIV specialist if:

- 1) The viral load fails to become suppressed below 200 copies at 4-6 months
- 2) The viral load initially falls below 20 copies but later rebounds to greater than 200
- 3) The patient is a pregnant woman
- 4) The patient is co-infected with Hepatitis B or C

More information about antiretroviral therapy can be accessed at this web page under the **DHHS Antiretroviral Guidelines**:

<https://aidsinfo.nih.gov/guidelines>

Another excellent resource on antiretroviral therapy is the **National HIV Curriculum** developed by the AIDS Education Training Center and University of Washington:

<https://www.hiv.uw.edu>

The **UCSF HIV Warm-Line** number for consultation on complex antiretroviral therapy questions is 1-800-933-3413.

Finally, a special monthly teaching and clinical management advice resource is the **Indian Country HIV ECHO Teleconference** held the second Wednesday of every month at Noon Mountain Time. This teleconference which is co-sponsored by IHS and University of New Mexico is designed to get Indian Health Service providers comfortable providing care to people living with HIV. Please contact IHSECHO@unm.salud.edu to connect with this service.

Prevention of Opportunistic Infections_(ref 2)

Prophylactic therapy for HIV associated opportunistic infections has made a significant impact on HIV morbidity and mortality. Preventive therapy is indicated for the following infections as per the DHHS guidelines:

<u>Organism</u>	<u>CDC count cutoff</u>	<u>Drug regimens (in order of preference)</u>
Pneumocystis	≤ 200	1)TMP/SMZ DS or SS 1 po daily 2) TMP/SMZ DS 1 po 3x/wk 3) Dapsone 100 mg po daily

		4) Atovaquone 1500 mg po daily 5) Aerosolized pentamidine 300 mg per month.
Toxoplasmosis	≤100 & (+) serology	1) TMP /SMZ DS 1 po daily 2) Dapsone 50 mg po daily <i>plus</i> Pyrimethamine 50 mg po weekly <i>plus</i> leukovorin 25 mg po weekly.
<u>Mycobacterium avium</u> complex	≤ 50 and not starting ART (check of AFB Blood Cx prior to Rx)	1) Azithromycin 1200 mg po weekly or 2) Clarithromycin 500mg po bid

Institution of prophylactic therapy should be based on the most recent CD4 count. Preventive therapy can be stopped for the following organisms in patients who were receiving once there is immune reconstitution:

Criteria for stopping primary prophylaxis

<u>Pathogen</u>	<u>Criteria</u>	<u>Comment</u>
Pneumocystis	CD4 count >200 for 3 months	Restart when CD4 < 100 or CD4 100-200 and HIV RNA is detectable
M. avium	Effective ART initiated	Restart when CD4 < 50 only if not on fully suppressive ART
Toxoplasmosis	CD4 is >200 for 3 months	Restart when CD4 < 100 or CD4 100-200 and HIV RNA is detectable

Health Maintenance (ref 4)

Partner notification:

Referrals should be made routinely to the local tribal, or other local government HIV partner notification program for contact investigation. Urgent testing of contacts and referral of HIV positive contacts for evaluation and treatment is mandatory. Partners who are found to be HIV

negative are eligible for PreExposure Prophylaxis for HIV (PrEP) and should be referred for evaluation.

Case Management/Home Care

Optimal HIV care should involve immediate enrollment in a local case management program. This could involve a designated HIV Nurse Case Manager and HIV home care technicians if available at the local facility. Another option would be to work with preexisting resources such as local IHS Public Health Nursing programs and tribal Community Health Representative programs. Many states and locales have a local HIV case management program that can do outreach to assist HIV positive persons. Teaching resources for use in the clinic and field are available on the Indian Health Service HIV home page at

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Eye Care:

HIV positive patients need an annual eye clinic check-up to rule out HIV related eye disease.

Dental Care:

HIV positive patients need an annual dental clinic check-up to rule out HIV related oral disease.

GYN Care:

HIV positive women need 2 PAP smears six months apart after HIV diagnosis then annual screening if negative. Routine mammography is indicated as per the standard guidelines for the general population starting at age 40.

Colorectal/Anal Cancer Screening:

HIV positive patients need an annual anal and rectal exam to rule out anal cancer and STD's. Annual screening with anal PAP smears is encouraged. Patients with an abnormal anal PAP smear should be referred to an experienced surgeon for management with high resolution anoscopy. Colorectal cancer screening should be done as indicated by guidelines for the general population starting at age 45.

STD Screening:

An annual RPR and urine gonorrhea/chlamydia nucleic acid probe test is indicated on all patients. Men Who Have Sex with Men should also have an annual pharyngeal and anal GC/Chlamydia swab nucleic acid probe test. It is prudent to offer pharyngeal and rectal testing for gonorrhea and chlamydia on an annual basis to trans-gender and cis-gender women who have receptive oral or anal intercourse. Patients with multiple sexual partners can be tested more frequently (up to quarterly).

Lipid Screening

HIV positive patients need annual lipid screening plus screening after a change in antiretroviral therapy. Atorvastatin or Rosuvastatin, are preferred agents for treating hyperlipidemia in HIV positive persons. HIV is now recognized by the AHA as a risk modifier for atherosclerotic coronary vascular disease. Moderate dose statin therapy should be considered for HIV positive persons with an ASCVD 10 year risk score of 5% or more per current AHA treatment guidelines.

Bone Health

DEXA scans are indicated for post-menopausal women and for men age 50 or greater with HIV, especially those on Tenofovir. Vitamin D level testing is recommended once and periodically as indicated.

TB screening and management of Latent Tuberculosis Infection (LTBI):

A TB skin test (PPD) or Interferon Gamma Release Assay (IGRA) such as the Quantiferon test should be done at diagnosis and annually. Quantiferon testing offers the advantage of a single visit, saving gas money for the patient and clinic outreach staff. A symptom review and CXR are mandatory to show there is no active tuberculosis before making the diagnosis of Latent TB Infection. Sputum specimens for AFB smear and culture should be obtained if the patient has symptoms such as cough, fever or night sweats to rule out TB even if the CXR is normal. Isoniazid monotherapy for 9 months OR Isoniazid and Rifapentine (3HP) weekly for 12 weeks are indicated for all positive PPD tests greater than 5 mm induration (not 10 mm) or positive IGRA tests in HIV positive patients. A Raltegravir based ART regimen is preferred if 3HP is used. All HIV positive patients receiving INH need pyridoxine 50 mg po daily to prevent neuropathy. Consultation with an HIV-TB specialist is recommended for all persons with TB-HIV coinfection.

Nutritionist Consultation:

HIV positive patients should see a nutritionist yearly at a minimum. If the patient is malnourished or diabetic, more frequent monitoring is indicated.

Hepatitis Testing:

Baseline testing for hepatitis A, B and C is indicated. Annual testing for Hepatitis B and C of patients with high risk behavior (MSM or injection drug use) should be offered unless already immune or infected.

Vaccines:

All patients should be immunized with hepatitis B, influenza, TdAP, meningococcal and pneumococcal vaccines. Patients should receive both the conventional PPSV-23 (Pneumovax™) and the PCV-13 (Prevnar™) vaccines. PCV 13 is given first followed 2 months later by PPSV-23 vaccine. A second dose of PPSV-23 is given 5 years later. All patients require a hepatitis B surface antibody test after immunization to document immunity. A double dose Hep B vaccine given at 0, 1, 2 and 6 months may be given to HIV positive patients who have not responded to an initial standard vaccine series of three injections. Hepatitis A immunity should also be

documented and if non-immune the hepatitis A vaccine series should be given. According to the ACIP, HPV vaccine should be given to males and females through age 26 but the FDA allows for vaccination through age 45. Varicella primary vaccination may be considered for adults who are varicella seronegative and have a CD4 count greater than 200. Shingrix is not yet routinely recommended for HIV positive adults by the CDC. Menactra (MenACWY) vaccine is recommend for all HIV positive adults with repeat vaccine at 2 months then every five years afterward.

Mental Health:

All patients should be screened for depression, anxiety, suicidal ideation and substance use disorder at every visit. Patients with a positive mental health/substance use screen should be referred to a mental health provider or substance use disorder counselor. Domestic violence screening is indicated at every visit for both men and women with appropriate referrals if screening is positive.

Spiritual Health:

Patients should be asked about their spiritual health during clinic visits and referred to a medicine man, minister or other appropriate spiritual health provider if desired.

References:

1. Adult and Adolescent Antiretroviral Guidelines:
<http://aidsinfo.nih.gov/guidelines>
2. Adult and Adolescent Opportunistic Infection prevention and treatment guidelines:
<http://aidsinfo.nih.gov/guidelines>
3. Primary Care Guidelines for the Management of Persons Infected with HIV:
<https://www.idsociety.org/practice-guideline/primary-care-management-of-patients-infected-with-hiv/>
4. National HIV Curriculum:
<https://www.hiv.uw.edu>

HIV Primary Care Screening Checklist

Baseline evaluation:

- CD4 count
- HIV Viral Load
- HIV Genotypic Antiretroviral Resistance Test
- RPR
- GC/CT (urine test for all, pharyngeal/rectal if there is exposure)
- Hepatitis A IgM and total Ab, HBsAg, HBsAb, HCV Ab
- Quantiferon or Tuberculosis skin test (CXR if positive)
- Toxoplasma Antibody
- Varicella Antibody if no documented history of chickenpox/shingles
- CMP/CBC
- Lipid panel
- G6PD test
- Hemoglobin A1c and fasting glucose
- UA
- Urine Pregnancy if female
- Cervical Pap smear (twice in first year 6 months apart)
- Anal Pap smear

Quarterly evaluation

- CD4 count
- HIV Viral Load
- CMP
- CBC

Annual Evaluation

- RPR
- GC/CT (urine test for all, pharyngeal/rectal if there is exposure)
- Hepatitis A IgM and total Ab, HBsAg, HBsAb, HCV Ab
- Quantiferon or Tuberculosis skin test (CXR if positive)
- UA
- Eye Exam
- Dental Exam
- Cervical PAP smear (not every 3 years if HIV positive)
- Anal PAP smear

Other periodic screening

- DEXA scan
- Colorectal Cancer Screening