FEDERAL BUREAU OF PRISONS
CLINICAL PRACTICE GUIDELINES
MANAGEMENT OF HIV INFECTION
OCTOBER, 2000

PURPOSE

The BOP Clinical Practice Guidelines for the Management of HIV Infection provide guidelines for the evaluation and treatment of federal inmates with HIV infection.

REFERENCES

NOTE: References in **bold** text are key references which should be maintained in conjunction with these guidelines. These references provide additional specific information and recommendations not contained in this document.

HIV Classification

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Prophylaxis of Opportunistic Infections

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Maternal Health and Reducing Perinatal Transmission

U.S. Public Health Service task force recommendations for the use of antiretroviral drugs in pregnant women infected with HIV-1 for maternal health and for reducing perinatal HIV-1 transmission in the United States, February 25, 2000, (updated regularly at http://www.hivatis.org).

Infection Control/Post-exposure Prophylaxis

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Centers for Disease Control and Prevention, Management of possible sexual, injecting-drug-use, or other nonoccupational exposures to HIV, including considerations related to antiretroviral therapy, *MMWR*, 1998;47(RR-17).

DEFINITIONS

Airborne precautions are protective measures used to prevent the spread of infections transmitted by inhalation of bacteria that remain suspended indoors in poorly circulated air. Precautions include the wearing of appropriate respiratory protection (i.e., HEPA or N-95 respirators) for persons who come in contact with contaminated air and the isolation of contagious inmates in a private room with monitored, negative air pressure in accordance with CDC guidelines and Bureau policy.

Adherence is the willingness and ability of a patient to take a prescribed treatment regimen (> 95% adherence to antiretroviral medications is necessary for maximal HIV RNA suppression).

CD4+ T-cell is a T cell lymphocyte essential for human cellular immunity. Progressive HIV infection is associated with declines in CD4+ T-cells, immunosuppression, and susceptibility to opportunistic infections.

Clinician is a physician or mid-level provider.

Contact precautions are protective measures to prevent the spread of infections transmitted by direct hand or skin-to-skin contact with body fluids. Precautions include the wearing of personal protective equipment and the isolation of potentially contagious inmates in a single-cell room.

Droplet precautions are protective measures used to prevent the spread of infections transmitted by the dispersal of large droplet sprays as with certain respiratory viral infections that can be transmitted during face-to-face contact. Precautions include the wearing of a protective mask for persons who come in close contact with infected inmates, and the isolation of potentially contagious inmates in use of a private or single-cell room.

EIA is Enzyme Immunoassay, a laboratory test for detecting antibodies.

HIV RNA test is a laboratory assay used to quantatively measure the presence of HIV viral particles in serum, expressed as copies per milliliter (cps/mL). HIV RNA levels are measured for the staging of HIV infection and therapeutic monitoring. Standard and ultrasensitive assays are available.

HIV viral load or viral burden is the quantity of HIV RNA (HIV virus) that is measurable in the blood.

Immune reconstitution is regaining functional CD4+ T-cells (host cellular immunity) following treatment of a previously immunocompromised condition such as AIDS. Immune reconstitution in the context of HIV infection results from effective antiretroviral therapy and may paradoxically be associated with inflammatory reactions to certain pathogens such as *M. tuberculosis*, cytomegalovirus, and *M. avium* complex.

Non-occupational exposures refer to exposures to HIV that occur outside the performance of assigned work-related duties. Non-occupational exposures include unprotected sex, sharing of injection drug use equipment, or sharing other puncture-type devices such as tattoo equipment that could transmit infected blood.

Occupational exposures refer to reasonably anticipated contacts with HIV infected blood or other potentially infectious materials that may result from the performance of assigned work-related duties.

Primary prophylaxis is the provision of a treatment to prevent a specific infection in a person who is at risk for the infection, but who has not previously been infected.

Resistance testing for HIV refers to genotypic and phenotypic assays that assess HIV resistance to specific antiretroviral drugs. Genotypic assays measure specific mutations to viral enzymes (reverse transcriptase/protease). Phenotypic assays measure the ability of HIV to grow in various concentrations of antiretroviral drugs.

Secondary prophylaxis is the continued provision of antibiotics following the successful treatment of a specific infection in order to prevent the recurrence of the infection.

Standard precautions are protective measures used for all inmate contacts and situations to prevent the spread of infections transmitted by potentially contaminated blood and body fluids. Precautions include the wearing of gloves and other personal protective equipment(personal protective equipment should be an

impervious barrier) when soiling is likely; and procedures for protective handling (handling includes the use of puncture-resistant devices and leak-proof protection) of contaminated surfaces and equipment.

Undetectable HIV is the measurement of HIV RNA at levels that are below the level of detectability of specific assays with common thresholds of < 400-500 copies/mL; and < 20-50 copies/mL (ultrasensitive). The goal of antiretroviral therapy is to achieve viral suppression to undetectable levels, preferably with an assay with the lower threshold of < 20-50 copies/mL.

PROCEDURES

1. DIAGNOSIS

The following inmates are at high risk for HIV infection or have clinical indications for HIV testing and should be considered for diagnostic evaluation in accordance with Bureau policy when risk factors for HIV infection are identified:

- Persons who have injected drugs

- Men who have had sex with men

- Regular sex partners of persons at risk for HIV infection

- Inmates with a history of syphilis, sexually transmitted diseases, sexual abuse, or prostitution

- Inmates with hemophilia and any inmate who has received blood products between 1977 and May, 1985

- Pregnant women

- Persons with active tuberculosis or a positive tuberculin skin test

- Inmates with signs or symptoms of acute HIV infection or HIV-related conditions

Presentenced inmates with an uncertain duration of incarceration should be tested for HIV infection when symptomatic or when indicated for specific medical reasons.

All inmates tested for HIV infection should receive individual, confidential, pretest and post-test counseling by qualified health care personnel in accordance with BOP policy using the appropriate forms for HIV counseling and documentation (BP-s489.061 - 492.061). Counseling includes information on HIV

transmission and methods for preventing the spread of the virus while in prison and upon release to the community.

The diagnosis of HIV infection is ordinarily determined by a positive EIA for HIV antibodies that is confirmed by immunoblot (Western blot) analysis. The confirmatory Western blot requires three major viral proteins: the core protein (p24) and two envelope proteins (pg41) and (pg120/160). Results of HIV Western blots are interpreted as follows:

- NEGATIVE: no bands on Western blot

- POSITIVE: at least two of the three major bands present

- INDETERMINANT: one of the three bands on Western blot

The standard EIA and Western blot assays are > 99.9% specific and sensitive for detecting HIV infection. False negative, false positive, and indeterminant results are uncommon but have been documented.

FALSE NEGATIVE HIV test results can occur for the following reasons:

- **Recent acute HIV infection**: During the "window" period (the time between new infection and the development of HIV antibodies), HIV EIA tests may be negative. On average this time delay from recent infection to positive serology averages 21 days, but can be 6 months or greater in rare cases.

- **Seroconversion**: Persons with documented HIV infection can lose HIV antibodies either with late stage disease (AIDS), or with immune reconstitution with effective antiretroviral therapy.

- **Agammaglobulinemia** (low antibodies)

- **Infection with unusual strains of HIV** such as O subtype, N subtype, or HIV-2. O and N subtypes are extremely rare variants of HIV-1. HIV-2 occurs primarily in West Africa. Standard HIV EIA tests are falsely negative in 20-30% of persons infected with HIV-2. Specific tests are available for testing for HIV-2.

FALSE POSITIVE HIV test results are extremely uncommon, but can occur rarely from autoantibodies. Most cases of false positive HIV test results occur in persons who have received investigational HIV vaccines or through clerical errors.

INDETERMINANT HIV test results are usually associated with a single p24 band on Western blot analysis and with the following conditions:

- **Seroconversion** - antibodies usually become positive within 2 to 3 months of infection

- **Infection with unusual strains of HIV**: HIV-2 infection or HIV-1 subtypes O or N

- **Autoimmune disease and malignancies** with cross-reacting antibodies

- **Experimental HIV vaccine recipients**: may develop cross-reacting antibodies

- **Advanced HIV infection** (AIDS) from loss of HIV antibodies

Inmates with indeterminant HIV test results should be referred to a physician for further evaluation in accordance with the following guidelines:

- Physician interview for HIV infection risk factors, symptoms of HIV infection and AIDS, and causes of indeterminant HIV test results

- Physician evaluation of the inmate for conditions that may result in an indeterminant test result when clinically indicated based on the inmate's history and examination

- Repeat HIV testing in 3 and 6 months

- If the HIV test result remains indeterminant at 6 months, and the inmate has no risk factors for HIV infection, the inmate should be reassured that HIV infection is extremely unlikely. If HIV infection is suspected, despite indeterminant HIV test results, BOP medical referral center laboratory personnel should be consulted for further evaluation of the test results.

Acute HIV infection is diagnosed by detecting plasma HIV RNA with a negative or indeterminant HIV antibody test. HIV infection is confirmed by repeating the HIV Western blot serology 2 to 4 months after the initial test. Acute HIV infection is frequently undetected by the evaluating clinician. The clinical signs of fever, pharyngitis, and lymphadenopathy that are associated with acute HIV infection, are usually present, but frequently unreported or attributed to other etiologies. Less common manifestations of acute HIV infection include thrush, diarrhea, aseptic meningitis, facial palsy, Guillain-Barre syndrome, and

cognitive impairment. Testing for acute HIV infection should be pursued for inmates with a suggestive clinical presentation or definitive history of a recent exposure to HIV.

2. HIV NATURAL HISTORY, CLASSIFICATION, AND REPORTING

The natural history of HIV infection is well defined. Acute HIV infection results in marked HIV viremia with a rapid decline in CD4+ T-cells that is frequently associated with an infectious mononucleosis-type syndrome characterized by fever, rash, lymphadenopathy and fatigue. Clinical recovery is associated with an avid immune response with a an increase in CD4+ T-cells, resulting in a reduction in HIV viremia and the establishment of a viral load "set point". Over time the CD4+ T-cell count gradually declines in persons chronically infected with HIV, whereas HIV RNA levels gradually increase. In the absence of antiretroviral therapy, the average time from acute HIV infection to late stage HIV infection or AIDS is 10 years. AIDS is associated with marked immunosuppression with a CD4+ T-cell count $< 200/mm^3$, the development of opportunistic infections, neurologic complications, certain malignancies, and wasting syndrome. Without antiretroviral therapy or prophylaxis against opportunistic infections, the median survival after the development of an AIDS-defining illness is approximately one year. In treated patients, antiretroviral therapy markedly prolongs life and prevents the development of AIDS. Although antiretroviral therapy can suppress plasma HIV RNA to undetectable levels for years, viral rebound occurs within 12 weeks of stopping therapy in nearly all patients.

HIV classification is based on clinical symptoms, specific diagnoses associated with HIV infection, and the CD4+ T-cell count and percentage. All inmates newly diagnosed with HIV infection should be classified in accordance with the Centers for Disease Control and Prevention (CDC) classification system as outlined in Appendix 1: 1993 Revised CDC Classification System for HIV Infection. HIV risk factors and classification should be documented on the Bureau's HIV Classification Form, BP-s638.060. Reclassification and updated documentation of an inmate's HIV reclassification is indicated only when an inmate progresses to a more advanced stage of HIV infection, **not** during each evaluation or with clinical improvement. Reporting of HIV infection within the Bureau of Prisons and to State health authorities should be in accordance with Bureau policy and State laws and regulations.

3. MEDICAL EVALUATIONS

Baseline and periodic evaluations for inmates diagnosed with HIV infection are summarized in Appendix 2: Medical Evaluation for Inmates with HIV Infection by Immunologic Status.

Baseline Evaluation: Baseline evaluation by a physician for inmates newly diagnosed with HIV infection should include the following:

- Medical history including assessment of HIV risk factors

- Complete physical examination: including but not limited to a fundoscopic examination for retinopathy, oropharyngeal exam for thrush, careful skin exam for dermatitis, abdominal exam for hepatosplenomegaly, assessment of neurologic deficits, and pelvic examination and PAP smear for women

- Pap smears should be obtained in accordance with the following guidelines from Bartlett and Gallant (See references): "The cervix is scraped circumflexually using an Ayer spatula or a curved brush; a sample from the posterior fornix or the "vaginal pool" may also be included. The endocervical sample is taken with a saline-moistened cotton-tipped applicator or straight brush that is rolled on a slide and immediately fixed in ethyl ether plus 95% ethyl alcohol or 95% alcohol alone. The yield is seven-fold higher with the brush specimen. Important steps in obtaining an adequate sample:

    - Collect Pap smear prior to bimanual exam

    - Avoid contaminating sample with lubricant

    - Obtain Pap before testing for sexually transmitted diseases

    - If large amounts of vaginal discharge are present, carefully remove with large swab before obtaining Pap

    - Obtain ectocervical sample before endocervical sample

    - Small amounts of blood will not interfere with cytologic sampling but if bleeding is heavy, the Pap should be deferred

    - Collected material should be applied uniformly to a slide, without clumping, and should be rapidly fixed to avoid air-drying; if spray fixatives are used, the spray should be held at least 10 inches away from the slide to prevent disruption of cells by propellant."

- Referral for dental examination by a dentist for all inmates

- Psychology referral if clinically indicated (in addition

to mandatory referral made as part of post-test counseling)

- CBC/platelet count: 30-40% of persons with HIV infection have hematologic abnormalities

- CD4+ T-lymphocyte cell count and percentage: The measurement of CD4+ T-cells is essential for immunologic staging of inmates with HIV infection and for therapeutic monitoring and initiation of prophylaxis for opportunistic infections associated with HIV infection. The CD4+ T-cell count may decline with intercurrent illnesses and steroid administration. Splenectomy increases CD4+ T-cell counts. In addition, diurnal and analytical variations in measuring CD4+ T-cells are common. **CD4+ T-cell counts are subject to significant variability and can vary up to 30 percent on repeated measures in the absence of a change in the patient's clinical condition.**

The following caveats may assist the clinician in determining the inmate's immune status or help interpret CD4+ T-cell results:

- Any changes in the absolute number of CD4+ T-cells should be reviewed to determine if the percentage of CD4+ T-cells has also comparatively changed, since a decline in the absolute WBC count that is not related to HIV infection will often be reflected in a decline in CD4+ T-cells, while the percentage of CD4+ T-cells remains nearly constant.

- The median CD4+ T-cell count at the time of diagnosis of an AIDS-defining condition is 60 cells/mm^3.

- The immune status of inmates with HIV infection who refuse CD4+ T-cell assays can be roughly assessed by the absolute lymphocyte count. (A total lymphocyte count of <1,000/mL strongly correlates with a CD4+ T-cell count of <200/$mm^{3)}$.

- Inmates with HIV infection and unexplainable elevated CD4+ T-cells (poor correlation with clinical history/stage of infection) may have HTLV-1 co-infection. HTLV-1 is a retrovirus that increases the levels of CD4+ T-cells and is the cause of adult T-cell leukemia and tropical spastic paraparesis. HTLV-1 co-infection is associated with injection drug use (roughly 10% co-infection rate) and foreign-birth history (particularly high rates of co-infection noted in Haiti and Brazil).

- CD8+ T-cell counts do not predict clinical outcomes

- Quantitative plasma HIV RNA (viral load) measurement using FDA-approved method: Plasma HIV RNA should be measured at the time of diagnosis, before initiating antiretroviral therapy, and 3-4 weeks after any initiation or change in antiretroviral treatment. The same laboratory using the same HIV RNA assay should be utilized to minimize test variability in accordance with Bureau policy. The measurement of HIV viral burden within one month of an acute illness or immunization should be avoided due to false elevations. HIV RNA levels increase with progression of disease due to the lack of antiretroviral therapy, nonadherence to a drug treatment regimen, the development of viral resistance, or inadequate drug levels due to inadequate dosing or drug interactions.

- Serum electrolytes/creatinine/liver function studies: particularly important for detecting underlying hepatitis B or C in inmates with histories of injection drug use

- Syphilis serologies: screening RPR or VDRL with a confirmatory test (FTA) for positive screening tests (Note: false positive RPR/VDRL tests are common in persons with histories of injection drug use, a confirmatory test is essential)

- Toxoplasma IgG titer: (Note: IgM titers are not clinically useful) helps determine candidates for toxoplasmosis prophylaxis

- Fasting lipid profile prior to initiating antiretroviral therapy

- Hepatitis B and C serologies/vaccination - Inmates with HIV infection and risk factors for viral hepatitis should be screened for HBV and HCV infections, by measuring anti-HBc and anti-HCV antibodies respectively. Inmates with elevated liver transaminases should have HBsAg+ measured as well to determine if chronic HBV infection is present. Inmates without HBV infection with risk factors for acquiring HBV infection should receive hepatitis B vaccination in accordance with Bureau guidelines for the management of viral hepatitis.

- Tuberculin skin test/symptom review for TB symptoms (Note: anergy testing is not routinely recommended due to poor standardization of testing antigens and the failure of anergy testing to predict tuberculin skin test reactivity)

- Chest radiograph to evaluate for occult TB or other pathologies

- Pneumococcal vaccine: Pneumovax 0.5 mL IM x 1. Repeat vaccination if CD4+ T-cells were < 200 cells/mm^3 at the time of the initial vaccination and then subsequently increase to > 200 cells/mm^3; and consider repeat vaccination after 5 years of initial vaccination x 1 regardless of CD4+ T-cell levels.

- Influenza vaccine: 0.5 mL, IM in late autumn, repeated annually

- Comprehensive treatment plan, including subspecialty referrals as clinically indicated

Periodic Evaluations

The frequency of physical examinations for inmates with HIV infection by clinicians should be based on the inmate's immune status and other relevant clinical factors as determined by the responsible physician. Medically complex inmates and inmates with AIDS should be followed closely by a physician. Physical examinations should be targeted to identify the immunosuppressive complications of HIV infection consistent with the inmate's stage of disease. **Inmates should be reclassified according to CDC criteria if they progress to a more advanced stage of infection.**

Inmates' immunologic status should be assessed by the measurement of CD4+ T-cell counts and plasma HIV RNA levels using FDA-approved testing methods. The recommended frequency of routine CD4+ T-cell and HIV plasma RNA testing is based on the immune status of the patient as outlined in Appendix 2. The indications and frequency of other laboratory monitoring depends on the inmate's antiretroviral treatment regimen and prophylactic regimen for opportunistic infections. The measurement of p24 antigen, neopterin, and β-2 microglobulin levels are not routinely indicated. These markers are less reliable than plasma HIV RNA levels and do not add significant prognostic information for the clinician.

Other clinical monitoring parameters for certain inmates include the following:

- **Tuberculin skin tests** are indicated annually for inmates with measurements < 5 millimeters. Inmates with a tuberculin skin test of 5 millimeters or greater who refuse chemoprophylaxis should have annual chest radiographs, regardless of symptoms, to screen for occult tuberculosis.

- **Glucose-6-phosphate dehydrogenase (G-6-PD)** deficient inmates are susceptible to hemolytic anemia when exposed to oxidant drugs such as dapsone, primaquine, and less commonly sulfonamides. Baseline G-6-PD testing is **not** routinely recommended for inmates with HIV infection. G-6-PD testing should be reserved for at-risk inmates prior to initiating a potentially offending agent. African Americans, and persons from Mediterranean countries, India, and Southeast Asia are most susceptible. Hemolysis is usually self-limited, involving only the older red blood cells. A small subset of Mediterraneans have a genetic variant that causes severe hemolysis when exposed to oxidant drugs. Affected patients present with severe fatigue, dyspnea, anemia, high bilirubin and LDH, reticulocytosis, methemoglobinemia, and "bite cells" on peripheral smear. **During hemolysis, G-6-PD levels may be normal,** (false negative test) despite an inherent deficiency since young RBC cells are disproportionately present. Testing may not detect G-6-PD deficiency until 30 days after cessation of the offending drug.

- **Serum lipid analysis:** Inmates with cardiovascular risk factors or elevated baseline fasting triglyceride levels or LDL cholesterol levels should have lipid parameters monitored periodically while on antiretroviral therapy. The frequency of monitoring and the decision to medically intervene should be made on a case by case basis. More aggressive monitoring and treatment is indicated for inmates with multiple cardiovascular risk factors, pre-existing heart disease, diabetes, and other relevant complicating conditions.

- **Pap smears** should be repeated x 1 at 6 months if normal at baseline, and then repeated annually. Evidence of inflammation should prompt an evaluation for infection, followed by a repeat Pap in 3 months. Inmates with PAP smears with cellular atypia/ASCUS should have follow-up PAP smears without colposcopy every 4-6 months for 2 years until 3 PAP smears are negative. If atypia is noted a second time the inmate should be referred for colposcopy. Inmates with PAP smears with low grade squamous intraepithelia lesions (LSIL), or high grade squamous intraepithelial lesions (HSIL)/carcinoma *in situ* , or invasive carcinoma should be referred to a gynecologist for colposcopy and additional monitoring/treatment.

- Other monitoring parameters should be considered on a case by case basis depending on the inmate's medical problems and specific treatment regimen.

4. PROPHYLAXIS FOR OPPORTUNISTIC INFECTIONS

Prophylaxis for opportunistic infections may be indicated with significant immunosuppression (reduction in CD4+ T-cells) and is critical for preventing acute illnesses that require inmate hospitalizations. Prophylaxis should be prescribed in accordance with the most recent U.S. Public Health Service recommendations. Specific recommendations for prophylaxis for ***Pneumocystis carinii*** pneumonia, ***Toxoplasma gondii***, and ***Mycobacterium avium*** complex (MAC) are outlined in Appendix 3, Prophylaxis for HIV-Related Opportunistic Infections.

In addition, prophylaxis for other opportunistic infections should be initiated in accordance with the following:

- **Tuberculosis**: Prophylaxis for *M. tuberculosis* is routinely indicated for inmates with HIV infection who have tuberculin skin test results of **five millimeters or greater**. However, inmates with HIV infection who are close contacts of a confirmed contagious case of tuberculosis should receive prophylaxis regardless of tuberculin skin test status. The preferred prophylaxis regimen is isoniazid 900 mg orally, twice weekly (separated by at least two days) for 9 months (76 doses) of directly observed therapy plus pyridoxine 100 mg twice weekly (or 50 mg daily) with monthly assessments for clinical signs and symptoms of hepatotoxicity. For non-pregnant inmates with HIV infection, who are not taking antiretroviral therapy, two month therapy (60 doses) with rifampin (600 mg daily) plus pyrazinamide (20/mg/kg/day; maximum dose of 2 gms) is an alternative effective regimen, with assessments at 2, 4, and 8 weeks for signs and symptoms of hepatotoxicity. TB prophylaxis should be documented using the BOP Tuberculosis Chemoprophylaxis form, BP-s636.060, filed in section 2 of the medical record.

- **Cytomegalovirus**: Primary prophylaxis for cytomegalovirus (CMV) infection with oral gancyclovir is **not** routinely indicated despite severe immunosuppression (CD4+ T-cells < $50/mm^3$) and positive CMV IgG titers. Although gancyclovir has efficacy as a prophylactic agent, gancyclovir treatment does not increase survival, may promote CMV resistance, and requires a significant pill burden for the patient. Prophylaxis should be considered in this setting only for inmates with unique indications. CMV prophylaxis that is prescribed to inmates with previously diagnosed CMV retinitis (secondary prophylaxis) can be discontinued in consultation with the treating ophthalmologist if the CD4+ T-cell count increases to > 100-150/mm^3 for > 3-6 months, with sustained suppression of HIV RNA, a nonsight-threatening retinal lesion, and adequate vision in the contralateral eye. Close follow-up with an ophthalmologist is indicated.

- **Fungal infections:** Primary prophylaxis for fungal infections is not routinely indicated for patients with HIV infection despite low CD4+ T-cells. Although primary prophylaxis with fluconazole for oral candidiasis is effective, long term fluconazole may promote candidal resistance, is not cost effective, and is less important medically, since oral candidiasis is usually readily treatable with short term fluconazole therapy. Primary fluconazole prophylaxis for cryptococcosis (CD4+ T-cells < 50/mm^3) and primary itraconazole prophylaxis for histoplasmosis (CD4+ T-cells < 100/mm^3) may be considered for inmates with unique indications. **Inmates with prior cryptococcosis, histoplasmosis, or coccidioidomycosis require lifelong secondary prophylaxis.**

5. DISCONTINUING PROPHYLAXIS FOR OPPORTUNISTIC INFECTIONS

Effective antiretroviral therapy may result in immune reconstitution with clinically beneficial increases in CD4+ T-cells, but paradoxical inflammatory reactions to certain infections such as *M. tuberculosis*, *M. avium*, *herpes simplex*, *herpes zoster*, and *cytomegalovirus*. These acute reactions should not necessitate discontinuation of antiretroviral therapy and ordinarily respond to specific treatment interventions.

Effective antiretroviral therapy may result in improved cellular immunity and increases in functional CD4+ T-cells that significantly decrease the risk of opportunistic infections. Prophylaxis can be discontinued in accordance with the following guidelines:

- Primary and secondary prophylaxis for ***Pneumocystis carinii*** can be discontinued for inmates with **sustained** CD4+ T-cells ≥200/mm3 (at least 3-6 months). (Note: Data supporting discontinuing secondary PCP prophylaxis is not included in 1999 USPHS guidelines).

- Primary prophylaxis for ***Toxoplasma gondii*** can be discontinued for inmates with **sustained** CD4+ T-cells > 100/mm^3 (at least 3-6 months). Lifelong prophylaxis is required for inmates with previously diagnosed toxoplasmosis.

- Primary prophylaxis for ***Mycobacterium avium*** infection can be discontinued for inmates with **sustained** CD4+ T-cells > 100/mm^3 (at least 3-6 months). Lifelong prophylaxis is required for inmates with previously diagnosed MAC bacteremia.

6. INITIATING ANTIRETROVIRAL THERAPY

Antiretroviral therapy should be provided to inmates based on Department of Health and Human Services (DHHS) recommendations. Inmates with AIDS, or significantly elevated plasma HIV RNA levels or significantly depressed CD4+ T-cell counts are recommended for antiretroviral treatment as outlined in Appendix 4, Treatment Indications for Antiretroviral Therapy for HIV Infection. Additionally, inmates with acute HIV infection or documented HIV infection within the past 6 months, should be strongly considered for antiretroviral therapy on a case by case basis.

Asymptomatic inmates with CD4+ T-cells $\geq$ 350-500/mm^3 with HIV RNA levels > 20,000 cps/mL, who have never received antiretroviral treatment, should have HIV RNA levels confirmed with a second measurement prior to initiating first time antiretroviral therapy. Inmates with HIV RNA levels < 20,000 cps/mL (RT-PCR) with CD4+ T-cells of 200-499/mm^3, should have the depressed CD4+ T-cell count confirmed with a second measurement prior to initiating first time antiretroviral therapy.

The decision to initiate antiretroviral therapy should be weighed very carefully, since treatment is most effective with the initial regimen. The inmate's immunologic status, potential drug toxicities, length of anticipated incarceration, motivation, and history of previous adherence to medical treatments should all be considered before initiating treatment. Strict adherence to antiretroviral therapy is necessary for drug effectiveness and preventing drug resistance. In one report, HIV RNA levels were reduced to < 500 cps/mL in 81% of patients who were >95% adherent to the medication regimen; compared to only 24% of patients who were 70-80% adherent. Therefore, inmate education by clinicians, pharmacy, and nursing staff is critical before initiating complicated antiretroviral drug treatment regimens. Counseling should include a discussion of drug side effects, methods for managing side effects, instructions for taking scheduled medications by dose and time, and the need to report missed doses. **Mental health conditions should be evaluated, treated, and stabilized, prior to initiating antiretroviral therapy.**

The selection of an initial antiretroviral treatment regimen should ordinarily be consistent with one of the strongly recommended regimens listed in the DHHS guidelines (See http://www.hivatis.org). DHHS guidelines from January 2000, strongly recommend an initial antiretroviral regimen that includes one of the following four dual nucleoside reverse transcriptase inhibitor regimens (**d4T + 3TC, or d4T + ddI, or AZT + 3TC, or AZT + ddI**) **PLUS** either the non-nucleoside reverse transcriptase inhibitor (**efavirenz**); **OR** a single protease

inhibitor (**nelfinavir or indinavir**) **OR** the protease inhibitor combination (**ritonavir/saquinavir**). **(Note: Saquinavir-HGC [Invirase®] should NOT be prescribed as a single protease inhibitor). DHHS antiretroviral treatment guidelines should be accessed every 6 months and maintained with the Bureau's clinical practice guidelines, since DHHS guidelines are updated frequently and often include changes in recommended drug regimens.**

HIV resistance testing is not recommended for inmates with chronic HIV infection who are being started on antiretroviral treatment. Since long term adherence to treatment is critical, priority should be given to antiretroviral drug regimens that have fewer pills, fewer toxicities, and provide flexibility for switching to alternative potent treatment regimens in the future. FDA-approved antiretroviral medications, as of September 2000, are enumerated in Appendix 5, Nucleoside Reverse Transcriptase Inhibitors (NRTIs), Appendix 6, Nonnucleoside Reverse Transcriptase Inhibitors (NNRTIs), and Appendix 7, Protease Inhibitors (PIs); **however clinicians should specifically review DHHS guideline appendices that detail new FDA-approved antiretroviral medications, changes in antiretroviral dosages, drug side effects, monitoring parameters, and drug interactions.**

7. MONITORING EFFECTIVENESS OF ANTIRETROVIRAL THERAPY: HIV RNA (VIRAL LOAD) TESTING

The goal of antiretroviral therapy is to reduce plasma HIV RNA to undetectable levels (preferably with assay with threshold of detection to < 50 cps/mL) within 4-6 months of initiating treatment (predicted by a one log (10 fold) decline in HIV RNA levels within 8 weeks of initiating therapy). The higher the pretreatment HIV RNA levels, the longer the time required to achieve a viral nadir. **The HIV RNA level nadir strongly predicts the durability of antiviral suppression and long term effectiveness of the treatment regimen.**

A major advance in HIV treatment has been the development of plasma HIV RNA assays of increased sensitivity. These assays now detect as few as 20-50 cps/mL. Most physicians obtain viral load measurements that are "sensitive" to < 400 cps/mL, 2 to 8 weeks after initiating therapy, as the first follow-up indicator of a response to a new regimen. If a continued response is observed with the "sensitive assay", the "ultrasensitive" assay, (< 20 - 50 cps/mL), should be used when viral suppression has approached or surpassed the threshold of the "sensitive" assay. The expected response to an effective regimen is reduction of viral load by one log at eight weeks and no detectable virus at four to six months. The ultrasensitive assay confirms suppression of virus to the lowest detectable level and provides a benchmark for

monitoring future response to therapy.

8. INTERPRETING CHANGES IN VIRAL LOAD

Significant changes in viral load are expressed as one or more "log" increases or decreases. The simplest way to determine if viral load tests are significant is to determine if there is at least a ten-fold difference between them. For example, if the viral load has increased from <50 cps/mL to 500 cps/mL, this is a multiple of ten. If, on the other hand, the viral load increases from 400 to 3000, this is less than a one log increase and no changes in treatment should be considered based on this test. The sum of laboratory and biologic variability in these tests is between 30 and 50%; therefore only changes greater than this are considered meaningful.

9. SIDE EFFECTS OF ANTIRETROVIRAL MEDICATIONS

Drug dosing, side effect monitoring, and potential interactions should be carefully reviewed (see DHHS guideline appendices) prior to prescribing or changing antiretroviral therapy, and prior to initiating treatment for other conditions. Antiretroviral medication side effects include but are not limited to the following:

Bone marrow suppression: Anemia and/or neutropenia are strongly associated with zidovudine (AZT) usage. (Monitor CBC with differential 2, 6, and 12 weeks after starting treatment and then every 3-4 months if stable).

Hypergylcemia, new onset diabetes, and ketoacidosis have been associated with all of the protease inhibitors. If protease inhibitor therapy is effective, most physicians ordinarily treat the hyperglycemia rather than discontinue the protease inhibitor.

Hyperlipidemia with elevations in triglycerides and cholesterol, and fat redistribution syndromes (central obesity, dorsicervical fat accumulation, peripheral wasting) with or without hyperlipidemia have been associated with all of the protease inhibitors. Lipid abnormalities have been most closely associated with ritonavir. Marked triglyceridemia (>750 mg/dL) and clinically significant elevations in LDL-cholesterol (See Bureau treatment guidelines for managing lipid disorders) should be treated particularly with the coexistence of multiple cardiovascular risk factors, pre-existing heart disease, diabetes, or other relevant complicating conditions. No definitive treatments are recommended for the fat redistribution syndromes.

A hypersensitivity reaction is associated with **abacavir (ABC) rechallenge**. The hypersensitivity reaction is characterized by fever, morbilliform rash, dyspnea, nausea, and vomiting. Discontinuing abacavir and restarting the medication can result in life-threatening hypersensitivity reactions.

Lactic acidosis with hepatic steatosis is associated with all of the nucleoside reverse transcriptase inhibitors (NRTIs). Affected patients present with gastrointestinal complaints, weight loss, and dyspnea with acidosis and elevated ALT and CPK levels. Liver biopsy shows steatosis. Treatment is discontinuation of the NRTI. This adverse drug reaction is uncommon, but potentially life threatening.

Pancreatitis is associated with didanosine (ddI) usage and can be severe. (ddI is ordinarily not recommended for persons with a history of alcohol abuse).

Peripheral neuropathy is associated with zalcitabine (ddC), didanosine (ddI), and stavudine (d4T). (Use cautiously in inmates with co-morbid conditions also causing neuropathy, such as diabetes mellitus).

Nephrolithiasis and renal insufficiency are both independently associated with the protease inhibitor, indinavir. Toxicity is reduced by increasing fluid intake for the 3 hours following each dose of the medication.

Rash occurs most commonly with the nonnucleoside reverse transcriptase inhibitors (NNRTIs). The rash associated with nevirapine is partially aborted with dose escalation. Stevens-Johnson syndrome (severe exfoliative dermatitis) can occur with any of the NNRTIs, but is uncommon.

10. CHANGING ANTIRETROVIRAL TREATMENT REGIMENS

The lack of an increase in CD4+ T-cells or development of HIV-associated complications **with adequate viral suppression** is usually **not** an indication for changing antiretroviral therapy. Even when maximal viral suppression is not achieved, changing an inmate's antiretroviral regimen may or may not be advised, depending on the inmate's specific antiretroviral treatment history, stage of disease, and anticipated future adherence. Several studies have demonstrated that the majority of patients in the United States on antiretroviral therapy do no achieve viral suppression to < 500 cps/mL. However, even with suboptimal viral suppression, patients on recommended antiretroviral therapies may have increases in CD4+ T-cells and a reduced incidence of HIV-related complications. **Therefore,**

antiretroviral therapy should ordinarily be continued despite the lack of optimal efficacy for certain inmates.

Despite the warranted cautions for changing antiretroviral treatment regimens, a complete change in the antiretroviral drug regimen should be considered on a case by case basis for inmates who have not achieved or sustained undetectable HIV RNA levels. Since antiretroviral treatment options are limited and usually less effective than previously administered regimens, changes should be pursued carefully in accordance with the following guidelines:

- Review DHHS guidelines for changing antiretroviral therapy

- Repeat HIV RNA levels to confirm sustained elevations in HIV RNA

- Carefully review potential causes of virologic failure, including: lack of adherence to treatment regimen, drug side effects, drug interactions, poor absorption of medications, and the development of virologic resistance

- Review inmate's previous antiretroviral treatment history and adherence to treatment plans

- Consider single substitution of an antiretroviral agent because of drug side effects or adverse reactions, only if HIV RNA levels are significantly suppressed.

- **Obtain recommendations from infectious disease consultant or other physician with expertise in managing patients with HIV infection**

- Consider drug resistance testing, but note: **Resistance tests are valid only if performed while the inmate is taking the drugs being tested, and the viral load is greater than 1000 copies/mL.**

- Discuss with inmate alternative treatment options including benefits and risks of changing antiretroviral therapy to determine inmate's preference and motivation. **Acute medical problems, mental health conditions, active substance abuse, and poor institutional adjustment, should ordinarily be addressed before initiating a new antiretroviral regimen.**

11. RESISTANCE TESTING

Resistance testing is recommended on a case by case basis for

inmates who are being considered for an alternative antiretroviral treatment regimen because of suspected virologic resistance. Since both genotypic and phenotypic assays are poorly standardized and difficult to interpret, they should be utilized **selectively and strategically** (most likely to benefit the patient). Resistance testing most reliably identifies drugs that should be avoided, rather than drugs most likely to be effective. The need for resistance testing, the type of assay, the timing of testing, and the interpretation of the results should be determined in consultation with an infectious disease consultant or other physician with expertise in treating persons with HIV infection as well as applicable expert recommendations (See DHHS guidelines and recommendations of the International AIDS Society).

12. DISCONTINUING ANTIRETROVIRAL THERAPY

Antiretroviral therapy should ordinarily not be discontinued solely because of a lack of viral suppression, since even suboptimal virologic responses to antiretroviral therapy may increase CD4+ T-cells and prevent or delay clinical progression.

Continuing antiretroviral medications for terminally ill inmates may provide little clinical benefit and negatively affect quality of life. In such cases, discontinuing antiretroviral therapy should be considered on a case by case basis after thoroughly discussing treatment options with the inmate.

13. COMPLICATING MEDICAL CONDITIONS

Pregnancy - All pregnant women should be tested for HIV infection with or without known risk factors for HIV infection. The primary objective in treating pregnant women with HIV infection should be to both prevent clinical progression of HIV infection in the mother and reduce the risk of perinatal transmission. Specific antiretroviral therapies should be considered for pregnant women in accordance with the most recent DHHS treatment guidelines (http://www.hivatis.org) and in consultation with a physician with experience treating pregnant women with HIV infection. Pregnancy itself does not preclude aggressive treatment for HIV, however, specific treatment regimens are recommended based on their proven efficacy in pregnancy and the risk of teratogenicity. Hydroxyurea and efavirenz should specifically be avoided due to their teratogenic potential. When otherwise appropriate zidovudine (AZT) should be included in the regimen due to its known benefit in reducing perinatal transmission.

Tuberculosis co-infection - Inmates being treated for HIV infection who are diagnosed with active tuberculosis and latent

tuberculosis infection may require adjustments in their antiretroviral drug regimen. Anti-tuberculosis medications, particularly rifampin, interact significantly with many antiretroviral medications. Optimal antiretroviral and anti-tuberculosis treatment regimens should be determined on a case by case basis in consultation with a U.S. Public Health Service guidelines, and an infectious disease physician or other physician with expertise in treating tuberculosis with HIV co-infection. Persons with HIV infection and active tuberculosis, particularly when severely immunocompromised with AIDS, may present with atypical clinical presentations of tuberculosis such as noncavitary pulmonary infiltrates. Therefore, all inmates with HIV infection and pneumonic infiltrates should be evaluated for pulmonary tuberculosis.

Hepatitis C Co-infection - Antiretroviral therapy should ordinarily not be withheld because of HCV co-infection. Careful monitoring of liver transaminases is warranted with the initiation of treatment since liver inflammation can occur secondary to antiretroviral therapy itself. Co-infection with HIV may cause chronic hepatitis C to progress more rapidly to clinically significant liver disease. Treatment indications for hepatitis C in HIV-coinfected patients are poorly defined. Considerations for treatment are enumerated in the Bureau's Treatment Guidelines for Viral Hepatitis. Interferon/ribavirin therapy may exacerbate host immunosuppression and interact with antiretroviral medications. Ribavirin blocks the action of zidovudine (AZT) and stavudine, but other potential drug interactions are poorly understood.

Wasting syndrome - The CDC defines the HIV wasting syndrome as progressive, involuntary weight loss (10% reduction in baseline body weight) plus chronic diarrhea, chronic weakness, or documented fever in the absence of an explanatory concurrent illness or condition. Smaller reductions in weight (5-10%) without associated symptoms, however, may be clinically significant in persons with HIV infection, particularly when complicated by AIDS. Other potential causes of weight loss such as drug side effects, depression, and opportunistic infections associated with AIDS should be actively identified and treated. Effective antiretroviral therapy should be initiated or improved in order to maximize HIV RNA suppression. Oral nutritional supplements do not ordinarily provide any additional benefit to a healthy diet. Other FDA-approved treatments should be considered on a case by case basis.

14. DOCUMENTATION OF MEDICAL TREATMENT

Documentation of medical care for inmates with HIV infection is maintained in accordance with the following:

- CDC initial and updated HIV classifications are documented on the Federal Bureau of Prisons HIV Classification Form, S638.060, filed in section 6 of the medical record.

- The BOP HIV Chronic Care Clinic Flowsheet, S636.060, filed in section 2 of the medical record, is strongly recommended for tracking treatment and laboratory parameters for sentenced inmates with anticipated incarcerations of greater than 1 year.

- Treatment plans for baseline and periodic clinician evaluations should be documented in medical record progress notes.

15. TRANSITION TO THE COMMUNITY

Continuity of prescribed treatments, particularly antiretroviral medications, is medically critical for inmates released directly to the community or to community placement facilities, such as halfway houses. Preparation for transitional medical needs should be initiated, whenever feasible, 3 months prior to release in accordance with the following guidelines:

- Release planning should be coordinated with the inmate's case manager and community corrections staff in accordance with Bureau policy.

- A clinician should meet with the inmate to finalize the treatment plan and ensure that the inmate understands the importance of adherence to treatment and specific follow-up instructions.

- Specific efforts should be made by Bureau staff to coordinate access to federally funded drug assistance programs such as ADAP (AIDS Drug Assistance Program), and other recommended treatments as applicable such as mental health care and substance abuse programs.

- A consent for release of medical information should be obtained from the inmate in accordance with BOP policy so that the inmate's treatment plan can be discussed with the community health care provider.

- A supply of medications should be provided to the inmate prior to release or during community placement in accordance with Bureau policy.

16. INFECTION CONTROL MEASURES

Transmission: HIV is spread primarily through percutaneuous blood

exposures, such as injection drug use, transfusion of contaminated blood products or by organ transplantation (received prior to 1985). HIV is also transmitted through sexual contact, and perinatally from mother to child during pregnancy. HIV is not spread by sneezing, hugging, coughing, food or water, sharing eating utensils or drinking glasses, or through casual contact.

All inmates should be counseled during orientation to the institution and when appropriate during clinical evaluations of the importance of preventing blood exposures to others during activities of daily living. This includes: not sharing toothbrushes, razors, or other household items that may be contaminated with blood; and by refraining from prohibited behaviors that may transmit HIV, such as sharing injection drug use equipment, tattoo equipment, and having sexual contact with other inmates.

Inmates with known HIV infection should be counseled on the specific measures necessary for preventing further transmission of HIV to others during incarceration and upon release including the following recommendations:

- Do not shoot drugs

- Do not donate blood, body organs, or other tissue or semen

- Do not share personal items that might have your blood on them, such as toothbrushes, dental appliances, nail-grooming or clipping equipment, or razors

- Do not have sex while in prison, or have unprotected sex upon release to the community

- Do not share non-commercial tattooing or body piercing equipment

- Cover you cuts and skin sores to keep your blood from contacting other persons, and report to your physician should you have an open, draining wound

Inmates with known HIV infection should be managed while incarcerated in accordance with the following guidelines:

- Counseled regarding the importance of preventing the transmission of infections to others while in prison and upon release to the community

- Managed using standard precautions to prevent transmission when in contact with the inmate’s blood or other potentially infectious materials

- Managed using infection control practices in which non-disposable patient-care items are appropriately cleaned, disinfected, or sterilized based on the use; and measures are taken to prevent cross-contamination during patient care; i.e., dialysis, vascular access, cauterizing, dental procedures, etc., in accordance with Centers for Disease Control Guidelines on Handwashing and Hospital Environmental Control.

- Managed using appropriate airborne, droplet, and/or contact precautions when indicated for immunosuppressed inmates with HIV infection who have or may have acute secondary infections transmittable by respiratory contact, or by direct hand or skin-to-skin contact

Prevention: There is no vaccine available to provide protection against acquiring HIV infection. All activities in which exposure to infected blood may occur, should be considered potentially infectious. Inmates immunocompromised from HIV infection should be counseled on the following additional measures to prevent acquisition of secondary infections during incarceration and upon release:

- Always wash hands before eating, after touching contaminated clothing/bedding, after attending to personal hygiene, after gardening or other outdoor activities, after touching animals, or after touching any other contaminated items

- Wash fresh fruits and vegetables thoroughly before eating

- Avoid eating undercooked or raw meats

- Stop smoking

17. HIV POST-EXPOSURE PROPHYLAXIS (PEP)

Specific administrative, personnel, and medical procedures for implementing the CDC guidelines for HIV post-exposure prophylaxis should be outlined in the institution's exposure control plan for bloodborne pathogens. The institution’s procedures for providing HIV post-exposure prophylaxis to inmate workers should be included in orientation and training.

Inmate workers who experience occupational-related exposures to HIV-infected blood or other potentially infectious materials (OPIM) should be provided emergent counseling and treatment with post-exposure medications when indicated, and a follow-up evaluation by a qualified health care professional should be conducted in accordance with the following guidelines (**Specific**

expert consultation is available 24 hours a day, 7 days a week from the CDC hotline, (888)-448-4911).

- The injured skin or wound should be emergently cleansed with soap and running water for two minutes. Mild bleeding should be allowed to continue. Antiseptics, bleach, or other cleansing agents should not be used. Aspiration, forced bleeding, and wound incision are not recommended. Mucous membranes should be rinsed with water for two minutes. Exposed eyes should be flushed with water or saline for two minutes.

- The evaluating health care professional should interview the injured inmate worker to determine if a potential occupational exposure to HIV has occurred and the status of the source(s) involved in the exposure. CDC guidelines require the determination of an exposure code and a source code before deciding if PEP is indicated (See CDC algorithms for determining exposure codes and source codes as well as the summary of CDC guidelines in Appendix 8, HIV Post-exposure Prophylaxis Guidelines). Post-exposure prophylaxis is usually not indicated if the source of the exposure is not HIV-infected, unless there is evidence that the source-person had clinical evidence of HIV infection (e.g. acute retroviral illness, signs or symptoms of HIV infection) or recent high risk activity for acquiring HIV infection).

- The person whose blood or body fluids are the source of an occupational exposure should be evaluated for HIV infection in accordance with CDC guidelines and BOP policy. Blood and the following substances are considered potentially infectious for HIV: semen, vaginal secretions, cerebrospinal fluid, pleural fluid, peritoneal fluid, synovial fluid, unfixed tissue, certain lab specimens, and any substance contaminated by visible blood. Exposure to visibly uncontaminated urine, feces, and saliva does not require HIV post-exposure prophylaxis. Human bites involving blood are considered percutaneous blood exposures, however the risk of HIV transmission from these exposures is exceedingly low.

- If an exposure or questionable occupational exposure to HIV has occurred, the evaluating health care professional should immediately review the incident with the Clinical Director or other physician designee to validate the exposure and determine if HIV post-exposure treatment is indicated, to be considered, or may not be warranted in accordance with CDC guidelines, outlined in Appendix 8.

- The evaluating health care professional should provide counseling to the exposed inmate worker regarding HIV post-exposure indications in accordance with BOP physician orders and CDC guidelines.

- If no medical contraindications to treatment are identified, the inmate worker should be prescribed antiretroviral medications based upon the risk assessment. Inmates workers should be informed of the CDC recommendations including but not necessarily limited to the risk, prevention, and drug treatment information included in Appendix 9, HIV Post-exposure Prophylaxis Fact Sheet. **CDC guidelines recommend that HIV post-exposure prophylaxis be administered promptly, preferably within a few hours of exposure.**

- The provision of HIV post-exposure prophylaxis to inmates should be documented in the inmate worker's medical record, including the date and description of the exposure, counseling provided, emergency treatment rendered, and a signed informed consent or declination for emergent HIV post-exposure prophylaxis (form BP-S639.060).

- Inmates who present with possible non-occupational exposures to HIV, such as unprotected sex, sharing of needles with HIV-infected persons, or exposure from other traumatic injury, should also be evaluated for post-exposure treatment, and reinforced on measures for behavioral risk reduction. Since no definitive data currently exist to support the effectiveness of post-exposure prophylaxis for non-occupational exposures, the CDC does not recommend for or against post-exposure prophylaxis in these settings. The determination to provide post-exposure prophylaxis for nonoccupational exposures should be determined on a case by case basis per the CDC recommendations for prophylaxis after occupational exposures to HIV and the following considerations:

    - The characteristics of the reported exposure and the likelihood that the source is infected with HIV

    - The characteristics of the HIV positive source such as stage of HIV infection

    - The appropriateness of the time delay between the exposure and presentation for medical care

    - The ability of the exposed person to adhere to the antiretroviral therapy

- Inmates with occupational and nonoccupational exposures to HIV should have HIV antibodies measured at the time of exposure, and 6 weeks, 12 weeks, and 6 months after the exposure. A 12 month HIV antibody test is considered optional, unless clinically indicated (e.g. history of acute HIV syndrome following an exposure without seroconversion at 6 months). If the source is HIV seronegative, but engaging in behaviors at risk for transmission of HIV infection, follow-up HIV antibody testing at 3 and 6 months should be considered for the exposed inmates.

- All matters of nondisclosure/disclosure, and confidential handling of medical information pertaining to occupational and non-occupational exposure of inmates should be maintained according to BOP policy.

ATTACHMENTS

Appendix 1: 1993 Revised CDC Classification System for HIV Infection

Appendix 2: Medical Evaluation for Inmates with HIV Infection by Immunologic Status

Appendix 3: Prophylaxis for HIV-Related Opportunistic Infections

Appendix 4: Treatment Indications for Antiretroviral Therapy for HIV Infection

Appendix 5: Nucleoside Reverse Transcriptase Inhibitors (NRTIs)

Appendix 6: Nonnucleoside Reverse Transcriptase Inhibitors (NNRTIs)

Appendix 7: Protease Inhibitors (PIs)

Appendix 8: HIV Post-exposure Prophylaxis Guidelines

Appendix 9: HIV Post-exposure Prophylaxis Fact Sheet

Appendix 10: Resources: Prevention and Treatment of HIV Infection

Appendix 11: Self-Assessment - Management of HIV Infection

Appendix 12: Self-Assessment Answers - Management of HIV Infection

Appendix 1 - 1993 Revised CDC Classification System for HIV Infection

CD4+ T-cells/ mm^3	CD4+ (%)	A Asymptomatic	B Symptomatic Disease	C AIDS Indicator Conditions
≥500	≥29%	A1	B1	C1
200-499	14-28	A2	B2	C2
<200	<14	A3	B3	C3
		* acute (primary) HIV infection *PGL (persistent generalized lymphadenopathy)	Symptomatic conditions that are attributed to HIV infection; or the conditions have a clinical course complicated by HIV. Conditions include but are not limited to the following: * bacillary angiomatosis * oral candidiasis * vulvovaginal candidiasis: persistent (> 1 month or poorly responsive to tx) * cervical dysplasia (moderate-severe or CIS) * ITP * oral hairy leukoplakia * listeriosis * herpes zoster (involving more than 1 dermatome or 2 separate episodes)	* candidiasis: esophageal * coccidiomycosis: extrapulmonary * cryptococcoses: extrapulmonary * cervical cancer, invasive * cryptosporidiosis: chronic (> 1 month) * cytomegalovirus retinitis (or CMV in organs other than liver/spleen/nodes) * HIV encephalopathy * herpes simplex: esophagitis, genital/oral ulcers > 1 month * histoplasmosis: extrapulmonary/disseminated * isosporiasis: chronic diarrhea (> 1 month) * Kaposi's sarcoma * lymphoma: Burkitt's, immunoblastic, brain primary * MAC or *M. Kansasii*: extrapulmonary/disseminated * *M. tuberculosis*: pulmonary or extrapulmonary * other mycobacterium: extrapulmonary/disseminated * *Pneumocystis carinii* pneumonia (PCP) * pneumonia (recurrent: 2 or more episodes within 12 months) * progressive multifocal leukoencephalopathy (PML) * salmonella septicemia (> 1 occurrence) * toxoplasmosis (CNS) * wasting syndrome secondary to HIV infection

- Category B conditions take precedence over those in Category A; and Category C conditions take precedence over those in Category B.
- For classification purposes, the lowest accurate CD4+ T-lymphocyte count or percentage (not necessarily the most recent) should be utilized.

- Categories A3, B3, and C1, C2, and C3 are reported as AIDS cases.

Appendix 2 - Medical Evaluation for HIV Infection by Immunologic Status

Baseline Evaluation:
(1) history/PE including: fundoscopic exam/PAP smear for women (2) dental exam (3) CBC/platelets (4) CD4+ T-cell count, absolute and % (5) HIV RNA (viral load) (6) electrolytes/creatinine/LFTs (7) RPR/FTA (review tx history) (8) PPD/symptom review and chest x-ray (9) toxoplasma IgG (10) HBsAg/anti-HCV if LFTs abnormal (11) pneumococcal vaccine (12) hepatitis B vaccine if at-risk (13) lipid profile if started on antiretroviral medications

Periodic Evaluation:
(1) CBC/platelet count, LFTs/creatinine/electrolytes - q 3 months on anti-retroviral tx (2) periodic RPR as clinically indicated (3) Pap smear - at 6 months x 1 then annually (refer to gynecologist as indicated for colposcopy) (4) influenza vaccination annually (5) other laboratory tests as indicated.

CD4+ T-cells/mm^3	CD4+ T-cells assessment	Viral load	Clinician exam	Special Evaluations/Treatments
> 350	q 3-6 months	q 6 months off tx q 3-4 mon. on tx	q 3 months	Observe or initiate anti-retroviral tx depending on viral load Monitor CD4+ T-cell count q 3 months if 350-500 cells/mm^3
200-350	q 3-6 months	q 3-4 months	q 3 months	Initiate anti-retroviral therapy regardless of plasma HIV RNA levels
100-199	q 3-6 months	q 3-4 months	q 2 months	Initiate anti-retroviral therapy regardless of plasma HIV RNA levels Initiate PCP prophylaxis
50-99	q 3-6 months	q 3-4 months	monthly	Initiate anti-retroviral therapy regardless of plasma HIV RNA levels Initiate toxoplasmosis prophylaxis/maintain PCP prophylaxis Baseline fundoscopic exam by eye doctor to screen for CMV
0-49	q 6 months	q 3-4 months	monthly	Initiate anti-retroviral therapy regardless of plasma HIV RNA levels Maintain PCP/toxoplasmosis prophylaxis Initiate MAC prophylaxis Fundoscopic exam q 6 months by eye doctor to screen for CMV

- Plasma HIV RNA should be measured before and 2 - 8 weeks after initiation or changes in anti-retroviral tx and with worsening clinical or immune status.
- Effect of change in drug therapy on plasma HIV RNA should be evident in 2 - 8 weeks, but nadir may not be apparent for 3-4 months.
- Viral load should not be measured within one month of an acute illness or immunization (due to false elevations).

Appendix 3 - Prophylaxis for HIV-Related Opportunistic Infections

Pathogen	Drug	Dosage	Toxicities	Comments
Pneumocystis carinii Indications: (1) CD4+ T-cells <200/mm^3 (2) prior PCP (3) oral candidiasis	TMP-SMX (Bactrim, Septra) Dapsone Pentamidine	1 SS/day **(1st choice)** 1 DS/day 1 DS 3x/week 100 mg/day; or 50 mg BID 300 mg q month aerosolized (administer by Respirgard II nebulizer)	rash/fever/nausea leukopenia/hepatitis hemolysis methemoglobinemia bronchospasm/cough (responds to bronchodilator tx)	prevents toxo and bacterial infections monitor CBC q 3-4 months screen for G-6-PD deficiency obtain screening chest x-ray for TB can discontinue PCP prophy if CD4+ is > 200/mm^3 for 3-6 months with or without history of prior PCP
Toxoplasmosis Indication: Toxo IgG+ and CD4+ T-cells: <100 cells/mm^3	TMP-SMX (Bactrim, Septra) Dapsone + Pyrimethamine + Leukovorin	1 DS/day **(1st choice)** 1 SS/day 50 mg/day 50 mg/week 25 mg/week	rash/fever/nausea leukopenia/hepatitis hemolysis/anemia	repeat toxo IgG if previously negative when CD4+ T-cells < 100/mm^3 monitor for anemia/leukopenia with either regimen - CBC q 3-4 months can discontinue toxo prophylaxis if CD4+ count is > 100/mm^3 for 3-6 months if no prior toxoplasmosis
***Mycobacterium avium* *** Indication: CD4+ < 50 cells/mm^3 *R/O disseminated MAC infection with blood culture before giving prophylaxis	Azithromycin Clarithromycin Rifabutin	1200 mg/week **(1st choice)** 500 mg BID 300 mg/day	nausea/vomiting nausea/vomiting uveitis, arthralgias hepatitis	can discontinue prophy if CD4+ count is > 100/mm^3 for 6 months only if no history of prior MAC bacteremia uveitis when given with fluconazole creates rifampin resistance review drug interactions

- Routine primary prophylaxis for candidiasis is not indicated.
- Routine primary prophylaxis for CMV infection is not indicated: Screen routinely for retinitis.

Appendix 4 - Treatment Indications for Antiretroviral Therapy for HIV Infection

Immune Status	Treatment Options	Comments
Asymptomatic CD4+ T-cells ≥ 350/mm^3 **AND** - HIV RNA <20,000 cps/mL (RT-PCR) <10,000 cps/mL (bDNA)	Observe Initiate treatment on case by case basis for inmates with persistent CD4+ T-cell counts between 350-500/mm^3 and low plasma HIV RNA.	Monitor HIV RNA, CD4+ T-cell count, and clinical presentation for disease progression. Inmates with CD4+ T-cells between 350-500/mm^3 must be monitored closely - use low threshold for initiation of antiretroviral therapy. Treatment of asymptomatic patients with CD4+ T-cell counts > 500/mm^3 and low plasma HIV RNA levels is investigational.
Asymptomatic CD4+ T-cells 200-350/mm^3 **OR** HIV RNA: > 20,000 cps/mL (RNA-PCR) > 10,000 cps/mL (bDNA) Regardless of CD4+ count	Treatment per DHHS guidelines (Confirm depressed CD4+ T-cell count with second test before initiating treatment if plasma HIV RNA is < 20,000 cps/mL) (Confirm elevated plasma HIV RNA with second test before initiating first time treatment if CD4+ T-cell count is ≥ 350/mm^3.)	Highly aggressive antiretroviral therapy should be initiated in accordance with current DHHS guidelines. The goal of treatment is to reduce plasma HIV RNA to < 50 cps/mL within 4-6 months of initiating antiretroviral treatment (predicted by a one log (10 fold) decline in HIV RNA levels within 8 weeks of initiating treatment. Inmates who fail to attain undetectable plasma HIV RNA after 6 months of therapy should be considered for an alternative drug regimen. The HIV RNA level **nadir** strongly predicts the durability of antiviral suppression. >95% adherence to the antiretroviral regimen is necessary to have a 80% chance of achieving viral suppression 6 months after initiating therapy. Only 24% of treated patients achieve viral suppression when adherence to drug therapy falls to 70-80%. Adherence improves with inmate education, simplifying pill burden/treatment regimen, and effectively treating drug side effects. If change in antiretroviral therapy is indicated consult with physician with expertise in managing antiretroviral therapy.
Symptomatic with AIDS or AIDS-related infections; or Asymptomatic with CD4+ T-cell count < 200/mm^3 HIV RNA = any value	Treatment per DHHS guidelines	

Appendix 5 - Antiretroviral Therapy - Nucleoside Reverse Transcriptase Inhibitors (NRTIs)

Antiretroviral Tx	Dosage	Baseline Labs	Monitoring Labs	Toxicities	Comments
Zidovudine (AZT) Retrovir	200 mg TID or 300 mg BID	CBC/diff	CBC/diff 2,6, and 12 weeks after starting tx. every 3-4 months if stable	anemia neutropenia myalgia headache insomnia	marrow toxicity with gancyclovir reduce dose for moderate toxicities good CNS penetration
Lamivudine (3TC)	150 mg BID	none	none	minimal	combined with AZT as Combivir
Stavudine (d4T)	>60kg: 40 mg BID <60kg: 30 mg BID	CBC/diff	CBC/diff	neuropathy	reduce dose for renal disease based on creatinine clearance
Didanosine (ddI) Videx	>60kg:200 mg BID <60kg:125 mg BID; OR, 300-400 mg daily **take on empty stomach**	CBC/diff amylase liver function	CBC/diff amylase/liver function tests with GI symptoms	diarrhea nausea pancreatitis neuropathy	do not prescribe with history of pancreatitis or hx of alcohol abuse adjust dose in renal/hepatic disease
Zalcitabine (ddC) HIVID	0.75 mg TID	CBC/diff	CBC/diff amylase with GI symptoms	neuropathy stomatitis	reduce dose for renal disease
Abacavir	300 mg tabs 300 mg BID	none	none	hypersensitivity reaction (fever, rash, GI symptoms)	drug rechallenge after hypersensitivity reaction may be life threatening

- **Review updated antiretroviral drug information/interactions from DHHS guidelines**

Appendix 6 - Antiretroviral Therapy - Non-nucleoside Reverse Transcriptase Inhibitors (NNRTIs)

Antiretroviral Tx	Dosage	Baseline Labs	Monitoring Labs	Toxicities	Comments
Nevirapine Viramune	200 mg tabs - daily for 14 days, then if tolerated advance to standard tx. 200 mg BID	CBC liver transaminases	transaminases periodically	rash	incidence of rash reduced by gradual dose escalation whenever drug is stopped; restart at 200 mg daily for 14 day lead in period
Delavirdine Rescriptor	400 mg TID (100 mg tabs) no dose escalation required	CBC liver transaminases	CBC transaminases periodically	rash neutropenia with nelfinavir	multiple drug interactions: review all drugs, serious toxicities with cisapride, terfenadine, astemizole; absorption decreased with antacids; administer separately from ddI.
Efavirenz Sustiva	600 mg daily (200 mg caps)	CBC liver transaminases	CBC transaminases periodically	dizziness "disconnected feeling" rash - mild possible fetal anomalies	extremely potent antiviral effect not recommended for pregnant women serious toxicities with cisapride, terfenadine, and astemizole

- **Non-nucleoside analogues should never be prescribed as monotherapy or in combination with one another.**
- **Review updated antiretroviral drug information/interactions from DHHS guidelines**

Appendix 7 - Antiretroviral Therapy - Protease Inhibitors (PIs)

Antiretroviral Tx	Dosage	Baseline Labs	Monitoring Labs	Toxicities	Comments
Nelfinavir Viracept	750 mg TID; OR 1250 BID (250 mg caps)	transaminases glucose	transaminases glucose every 3-4 months	diarrhea	take with light snack or with meals
Indinavir Crixivan	800 mg q 8 h (400 mg caps)	transaminases renal function glucose fasting lipid profile	transaminases renal function glucose every 3-4 months	kidney stones nausea vomiting	take 1 hr before or 2 hrs after meal/not concurrently with ddI can take with skim milk or low fat meal drink at least 1.5 liters of water per day
Ritonavir Norvir	600 mg BID (100 mg caps) Initiate low dose then escalate to reduce GI effects	transaminases glucose fasting lipid profile	transaminases renal function glucose every 3-4 months	nausea vomiting parenthesis	take with food multiple drug interactions: PI most strongly correlated with lipid abnormalities
Saquinavir[1] Fortovase ***Use only with Ritonavir**	1200 mg TID (200 mg caps)	transaminases glucose fasting lipid profile	transaminases glucose every 3-4 months	diarrhea nausea	Fortovase 400 mg BID when given with Ritonavir 400 mg BID
Amprenavir Agenerase	1200 mg BID (150 mg caps)	transaminases glucose fasting lipid profile	transaminases glucose every 3-4 months		avoid high fat meals

- Do not use Saquinavir HGC (Hard Gel Capsule) (Invirase®)
- Dose escalation for ritonavir: 300 mg BID (day 1-2); 400 mg BID (day 3-5); 500 mg BID (day 6-13); then 600 mg BID
- Protease inhibitors may have **serious** interactions with certain drugs metabolized by the liver, e.g. astemizole, cisapride; review drug interactions carefully.
- All protease inhibitors may cause hyperglycemia, diabetic ketoacidosis, lipid abnormalities, and fat redistribution.

- **Review updated antiretroviral drug information/interactions from DHHS guidelines**

Appendix 8 - HIV Post-exposure Prophylaxis (PEP) Guidelines*

Exposure	Severity Factor	Source Status (+) titer *low*	*high*	*unk*	Counsel (Based on any one X)	Treatment Regimen
Percutaneous	▸ more severe	X	X		Recommend	▸ ZDV + 3TC + (*IDV* or *NFV*)
	▸ less severe *or* ▸ large volume 〉		X		Recommend	▸ ZDV + 3TC + (*IDV* or *NFV*)
	▸ less severe *or* ▸ large volume 〉	X			Recommend	▸ ZDV + 3TC
	▸ *any* factor above			X	Consider	▸ ZDV + 3TC
Mucous Membrane *(or compromised skin)*	▸ large volume		X		Recommend	▸ ZDV + 3TC + (*IDV* or *NFV*)
		X			Recommend	▸ ZDV + 3TC
				X	Consider	▸ ZDV + 3TC
	▸ small volume		X		Consider	▸ ZDV + 3TC
		X		X	PEP may *NOT* be warranted	
Skin *(intact skin)*	▸ higher volume or prolonged time 〉		X		Recommend	▸ ZDV + 3TC + (*IDV* or *NFV*)
		X			Recommend	▸ ZDV + 3TC
				X	Consider	▸ ZDV + 3TC
	▸ other	X	X	X	PEP may *NOT* be warranted	

NOTE: NO PEP NEEDED - once source is identified as HIV seronegative without symptoms of HIV infection, evidence of AIDS or clinical history of acute HIV syndrome, or evidence of recent high risk exposure to HIV infection. For cases involving exposures to HIV seronegative sources with symptoms of HIV infection or high-risk inmates who refuse HIV testing, PEP should be continued in accordance with CDC recommendations for exposures to sources with unknown HIV serostatus.

See attached definitions and refer also to CDC algorithms for HIV PEP, *MMWR* , Vol. 47 (RR-7), May 15, 1998

Appendix 8 - HIV Post-exposure Prophylaxis - Definitions*

EXPOSURE

(1) *Percutaneous*: is a needlestick or other sharp object penetration.
(2) *Mucous membrane*: eyes, nose, ear, mouth or compromised skin integrity (chapped, dermatitis, abrasion, wound).
(3) *Skin*: is intact skin only with higher volume of blood or prolonged contact time.

SEVERITY FACTOR

(1) *More severe: a* large-bore hollow needle, deep puncture, visible blood on device, needle in source patient's artery or vein.
(2) *Less severe* is solid needle or superficial scratch.
(3) *Large volume* is several drops, major blood splash and/or longer duration (i.e. several or more minutes).
(4) *Small volume* is a few drops, short duration.

SOURCE STATUS

(1) (+) *Positive titer/HIV infected:* (+) lab for HIV antibody or HIV RNA, or physician-diagnosed AIDS.
    a. *High titer* means advanced AIDS, primary HIV infection, high viral load or low CD4 count
    b. *Low titer* means asymptomatic and high CD4 count.
(2) Unk, *Unknown*: means the source status is unknown or unconfirmed.
(3) (-) *Negative*: lab documentation (-) HIV antibody, (-) PCR for HIV RNA, or HIV p24 collected at or near the time of exposure and no recent retroviral illness.

COUNSEL

(1) *Recommend* means the exposure represents an increased risk and use of PEP is appropriate.
(2) *Consider* means the exposure poses a negligible risk and use of PEP depends on whether the risk for drug toxicity outweighs the benefit of PEP decided by the exposed HCW and the clinician.
(3) *PEP may not be warranted* means the exposure type does not pose known risk. PEP is based on whether the risk for drug toxicity outweighs the benefit of PEP decided by the exposed HCW and the clinician.

TREATMENT

(1) *Basic two-drug regimen* is four weeks of Zidovudine (ZDV), 600 mg per day in two or three divided doses, (i.e., 300 mg twice a day, or 200 mg three times a day) and lamivudine (3TC), 150 mg twice daily, given orally.
(2) *Expanded three-drug regimen* is the basic regimen plus either indinavir (IDV), 800 mg every 8 hours, or nelfinavir (NFV), 750 mg three times a day, given orally.
(3) The optimal duration of drug therapy is unknown, but four weeks (28 days) of HIV PEP is recommended.

(Treatment regimens remain relatively unstudied with the exception of ZDV. Drug toxicity monitoring should include a CBC and renal and hepatic function tests at baseline and 2 weeks after starting PEP).

***Adapted from CDC guidelines: *MMWR,* Vol 45/No. 22, June 7, 1996 *and* Vol 47/No. RR-7, May 15, 1998.**

Appendix 9 - HIV Post-Exposure Prophylaxis Fact Sheet

Question #1 - What is my risk of acquiring HIV infection following an exposure?

Answer: The risk of acquiring HIV infection is related to the type and severity of exposure to blood or other potentially infectious body fluids that include: semen, cerebrospinal fluid, pleural fluid, peritoneal fluid, vaginal secretions, pericardial fluid and amniotic fluid. The average risk of acquiring HIV infection following an exposure from a puncture or cut in the skin is 0.3% (3 out of 1,000). The risk increases with the depth of the injury, if visible blood was present on the device causing the injury, if the device was previously in a patient's vein or artery, or if the source of the exposure was a person with AIDS. The risk of acquiring HIV infection after the exposure of mucous membranes of the eyes, nose, or mouth to HIV-infected material is 0.1% (1 out of a thousand). The risk of acquiring HIV infection after the exposure of intact skin to HIV-infected material is < 0.1% (The risk may be increased if the skin is not intact, or there is prolonged exposure with a large amount of blood). Every potential exposure should be discussed with a physician so that the specific risks of the particular exposure can be reviewed and assessed.

Question #2 - If I acquire HIV infection, can I be cured?

Answer: Presently there is no cure for HIV infection. Nearly all persons infected with HIV develop the acquired immunodeficiency syndrome (AIDS). Current treatments approved by the Food and Drug Administration for HIV infection prolong life and significantly delay progression to AIDS, but have not been proven to completely eradicate HIV. Prevention of HIV infection is critical.

Question #3 - If I have been exposed to HIV, what can I do to prevent infection?

Answer: Studies of health care workers exposed to HIV indicate that the medication, zidovudine (AZT), can reduce the transmission of HIV infection following an occupational exposure by nearly 80%. The Centers for Disease Control (CDC) currently recommends that persons at risk for acquiring HIV infection through occupational exposure to blood or other potentially infectious fluids be recommended or considered for treatment with 2 or 3 drugs effective against HIV for a one month period. The medications should be initiated as soon as possible following an exposure. The determination that prophylactic treatment should be recommended, considered, or may not be warranted is based on the type of exposure and the HIV status and condition of the source of the exposure.

Question #4 - If I have been exposed to urine, feces, or saliva from a person with HIV infection or AIDS should I take prophylactic medication?

Answer: The CDC does not recommend prophylactic treatment for HIV infection following occupational exposure to urine, feces, or saliva unless these substances are visibly contaminated with blood.

Appendix 9 - HIV Post-Exposure Prophylaxis Fact Sheet

Question #5 - Do the preventive medications have harmful side effects?

Answer: The toxicities of the drugs used to prevent HIV infection are largely unknown in persons without HIV infection. The drugs do have significant side effects that have been documented primarily in persons with HIV infection (see below). Drug toxicities can be significantly exacerbated by drug interactions. If you are currently taking prescribed medications for other health reasons you should review potential drug interactions and toxicities with your physician prior to taking preventive medications for HIV. In order to screen and monitor for potential drug toxicities you should have blood tests to evaluate your blood count, and kidney and liver function. Pregnancy itself should not preclude post-exposure prophylaxis, however, the known and unknown potential toxicities of antiretroviral medications on the mother, fetus, and newborn child should be discussed carefully with your physician. Pregnancy testing is recommended if you are of childbearing age, do not know if you are pregnant and/or have reason to believe you may be pregnant. When feasible, pregnant or potentially pregnant employees experiencing an exposure to HIV, should consult with their obstetrician or other personal physician when considering HIV post-exposure prophylaxis. Zidovudine (AZT) use in the second and third trimesters of pregnancy and early infancy, to date, has not been associated with serious adverse effects for the mother or her infant. Information on the safety of zidovudine (AZT) during the first trimester or other antiretroviral medications during any stage of pregnancy is limited.

Prophylactic Antiretroviral Medications:

Zidovudine (Retrovir) (AZT) - headache, muscle pains, nausea, sleeping problems, anemia
Lamivudine (Epivir) (3TC) - minimal symptoms
Indinavir (Crixivan) - nausea, vomiting, diarrhea, kidney stones; (take on empty stomach or with light snack and drink six 8 oz. glasses of water every day)
Nelfinavir (Viracept) - diarrhea, nausea (take with meals)

Question #6 - How will I know if I have been infected or protected from infection with HIV?

Answer: Your physician should measure your blood for HIV antibodies at the time of exposure, at 6 weeks, 12 weeks, and at 6 months. If you do not develop HIV antibodies by 6 months you are most likely not infected with HIV. In certain cases, your physician may measure HIV antibodies at 12 months as an extra precaution.

Question # 7 - Do I need to take any precautions during the 6 months I am awaiting confirmation that I have not newly acquired HIV infection?

Answer: Yes. You should follow these recommendations and maintain these precautions until advised that they are no longer necessary by your physician:

1. Report any unusual symptoms to your physician including fever, swollen glands, or rash.

2. Avoid exposing others to your blood or other potentially infectious body fluids. Use condoms during sexual intercourse. Do not share needles, razors, toothbrushes or other items that may be contaminated with your blood.

3. Use birth control measures to prevent pregnancy.

4. Do not donate blood, sperm, or other potentially infectious body substances.

Appendix 10 - Resources: Prevention and Treatment of HIV Infection

Department of Health and Human Services/U.S. Public Health Service

The HIV/AIDS Treatment Information Service (ATIS)
The central resource for federally-approved treatment guidelines for HIV and AIDS
1-800-HIV-0440 (1-800-448-0440)
Interagency website: *http://www.hivatis.org*

National AIDS Hotline: 1-800-342-2437(AIDS)
AIDS Treatment Information Service: 1-800-448-0440
Bilingual specialists are available Monday-Friday 9:00 AM -7:00 PM EST.

Centers for Disease Control National Prevention Information Network

P.O. Box 6003, Rockville, MD 20849-6003
Telephone 1-800-458-5231
Internet address: *http://www.cdcnpin.org*

PEP-Line, DHHS/CDC, managing work exposures with post-exposure prophylaxis.
Internet address: *http://www.epi-center.uscf.edu/warmline*
Post-exposure prophylaxis hotline/24 hours per day/7 days per week - **1-888-448-4911**

Health Resources and Services Administration (HRSA)

5600 Fishers Lane, Rm-746; Rockville, MD; 20857
Telephone: (301) 443-6652

AIDS Drug Assistance Program (ADAP); *Getting HIV/AIDS Care*, *State ADAP Contacts.*
Internet address: *http://hab.hrsa.gov/getting.html*

HRSA/AIDS ETC National HIV Telephone Consultation Service (Warmline),
800/933-3413, 7:30 AM - 5:00 PM PST (Mon-Fri)

U.S. Food and Drug Administration; Office of Special Health Needs

HFI-40; Rockville, MD; 20857
Telephone: 1-888-463-6332 (1-888-INFO-FDA)
Internet address: *http://www.fda.gov/oash/aids/hiv.html*

HIV/AIDS Information Center; Journal of the American Medical Association

Internet address: *http://www.ama-assn.org/special/hiv/hivhome.htm*

Pocket Guide to HIV/AIDS Treatment

Developed by Johns Hopkins University
Sponsored by HRSA/ AIDS Education Treatment Center's National Resource Center
Internet address: *http://www.aids-ed.org*

Appendix 10 - Resources: Prevention and Treatment of HIV Infection

Drug Treatment Directory

National Institutes of Health Center of Pharmacology
Internet address: *http:// www.cc.nih.gov/phar*

International AIDS Society

Treatment guidelines for HIV infection
Antiretroviral drug resistance testing guidelines
Internet address: *www.jama.ama-assn.org*

The Clinician's Educational Resource

An educational provider/professional healthcare resource; managed by World Health CME, with interactive services provided by InterActions Healthcare Communications.
Internet address: *http://www.HIVLine.com*

Substance Abuse and Mental Health Services Administration

Room 12-105 Parklawn Building; 5600 Fishers Lane; Rockville, MD 20857
Internet address: *http://www.samhsa.gov*

Self Assessment: Management of HIV Infection

Question #1
An inmate with a history of *Pneumocystis carinii* pneumonia and cerebral toxoplasmosis with a CD4+ count of 50/mm^3 (8% CD4+ T-cells) is started on AZT/3TC/efavirenz. Six months later he is asymptomatic with an undetectable viral load and a CD4+ T-cell count of 250/mm^3 with 14% CD4+ T-cells. Which of the following is true regarding HIV classification of this inmate?

A. The inmate should be reclassified to A2
B. The inmate should be reclassified to B2
C. The inmate should be reclassified to C2
D. The inmate should be reclassified to A3
E. The inmate should remain classified as C3

Question #2
Which of the following is false regarding acute HIV infection?

A. Most persons are asymptomatic
B. HIV test results may be negative
C. HIV test results may be indeterminant
D. Person may be misdiagnosed with infectious mononucleosis
E. Fever is the most common sign or symptom
F. May present with severe neurologic conditions

Question #3
Which of the following is not indicated during baseline evaluation of an inmate with HIV infection?

A. Chest radiograph
B. Plasma HIV RNA testing
C. Anergy panel
D. Vaccination against pneumococcal pneumonia
E. Toxoplasma IgG titer

Question #4
Which of the following is false regarding the initiation of prophylaxis for opportunistic infections associated with HIV?

A. Primary *Pneumocystis carinii* prophylaxis is routinely indicated if CD4+ T-cells are < 200/mm^3.
B. Primary toxoplasmosis prophylaxis is routinely indicated if CD4+ T-cells are < 100/mm^3.
C. Primary *Mycobacterium avium* prophylaxis is routinely indicated if CD4+ T-cells are < 50/mm^3.
D. Primary cytomegalovirus prophylaxis is routinely indicated for persons with a positive CMV IgG titer and CD4+ T-cells < 50/mm^3.
E. Primary prophylaxis for oral candidiasis with fluconazole is not cost effective.
F. The decision to prescribe prophylaxis for opportunistic infections is based on CD4+ T-cells independent of plasma HIV RNA levels.

Self-Assessment: Management of HIV Infection

Question #5
Which of the following statements is false regarding prophylaxis of opportunistic infections associated with AIDS?

A. The prophylactic agent of choice for *Mycobacterium avium* infection is azithromycin 1200 mg given once weekly.
B. The prophylactic agent of choice for *Pneumocystis carinii* pneumonia (PCP) is trimethoprim-sulfamethoxazole.
C. Hemolysis is a potential adverse reaction from dapsone.
D. Primary prophylaxis for *Pneumocystis carinii* pneumonia can be discontinued if CD4+ T-cells increase to > 200/mm^3 with effective antiretroviral therapy.
E. If an inmate has active tuberculosis, isoniazid should be continued indefinitely after completion of a multi-drug TB regimen.

Question #6
Antiretroviral treatment is NOT definitively indicated for which of the follow persons with HIV infection:

A. CD4+ T-cells are 250/mm^3
B. Inmate with toxoplasmosis brain abscess
C. Viral load is 50,000 cps/mL
D. CD4+ T-cells are 600/mm^3/plasma; HIV RNA is 5,000 cps/mL
E. CD4+ T-cells are 800/mm^3/plasma; HIV RNA is 100,000 cps/mL

Question #7
Which of the following statements is false regarding antiretroviral therapy?

A. ddI (didanosine) is associated with pancreatitis
B. Ritonavir and nevirapine require dose escalation
C. AZT commonly causes red cell microcytosis
D. Indinavir is associated with kidney stones
E. Indinavir is associated with renal insufficiency
F. All protease inhibitors can cause hyperglycemia and hyperlipidemia.

Question #8
Which of the following are potentially life threatening complications of antiretroviral therapy?

A. Restarting Abacavir in a patient who stopped taking the drug because of fever, vomiting, and shortness of breath.
B. Adding astemizole to a protease inhibitor containing regimen.
C. Continuing AZT in an inmate with lactic acidosis and hepatic steatosis.
D. Exfoliative dermatitis from nevirapine
E. All of the above

Self Assessment: Management of HIV Infection

Question #9
Which of the following statements is false?

A. Pregnant women with HIV infection may be candidates for antiretroviral therapy.
B. Efavirenz and hydroxyurea are potentially teratogenic.
C. An inmate on protease inhibitors should not be initiated on standard four drug therapy for tuberculosis.
D. Antiretroviral therapy reduces HIV perinatal transmission.
E. Tuberculosis with HIV co-infection ordinarily requires prolonged therapy with antituberculosis medications.

Question #10
Which of the following statements is false?

A. Inmate workers who have percutaneous exposures to HIV contaminated blood are candidates for emergent post-exposure prophylaxis with antiretroviral medications.
B. The risk of acquiring infection after a single percutaneous exposure to HIV is roughly 3 in a 1,000.
C. Antiretroviral medications rarely cause side effects when given as prophylaxis to persons previously uninfected with HIV.
D. Baseline testing for HIV infection in the exposed inmate worker is indicated at the time of exposure.

Question #11
On average, if your patients are 70-80% adherent to their antiretroviral drug regimen, what percentage will achieve HIV RNA suppression to < 500 cps/mL?

A. 20-30%
B. 40-50%
C. 70-80%
D. > 90%

Question #12

An inmate with a history of injection drug use, but unknown HIV status reports to sick call with fever, bilateral noncavitary interstitial infiltrates on chest x-ray and moderate dyspnea. The etiology consistent with this presentation is which of the following?

A. *Mycoplasma pneumoniae*
B. *M. tuberculosis*
C. *Pneumocystis carinii*
D. All of the above

Self Assessment Answers: Management of HIV Infection

Question #1 - Answer is E
HIV classification is based on clinical symptoms, specific diagnoses associated with HIV infection, and the CD4+ T-cell count and percentage. A person with a CD4+ T-cell count below 200 cells/mm^3 **or** < 14% with an AIDS indicator condition is classified as **C3.** Reclassification is indicated only when an inmate progresses to a more advanced stage of HIV infection, **not** with clinical or immunologic improvements.

Question #2 - Answer is A
Acute HIV infection commonly presents with fever, pharyngitis, and rash, with fever being the most common sign of infection, occurring in 96% of infected persons (See DHHS guidelines). Many cases go undetected or misdiagnosed since the presenting symptoms are commonly associated with other conditions such as infectious mononucleosis (Epstein-Barr virus infection). Acute HIV infection is diagnosed by detecting plasma HIV RNA with a negative or indeterminant antibody test for HIV. Unexplained neurologic conditions such as aseptic meningitis, facial palsy, and Guillain Barre syndrome warrant evaluation for acute HIV infection, since these conditions are associated with newly acquired HIV.

Question #3, Answer is C
All inmates diagnosed with HIV infection should have a baseline evaluation by a physician that includes a history and physical, laboratory tests, and immunizations. Anergy testing is no longer routinely recommended by the CDC, because of poor standardization of testing antigens and the failure of anergy testing to reliably predict tuberculin skin test reactivity.

Question #4, Answer is D
U.S. Public Health Service guidelines recommend prophylaxis of opportunistic infections based on the degree of immunosuppression as determined by CD4+ T-cell levels, independent of plasma HIV RNA levels (See Appendix 3). Primary prophylaxis with gancyclovir for CMV retinitis is not routinely recommended, since prophylactic gancyclovir does not improve patient survival, may promote CMV resistance, and requires a large pill burden for the patient. Primary prophylaxis for oral candidiasis with fluconazole, although effective, may promote resistant candidal infections and is not cost effective.

Question #5, Answer is E
Specific prophylactic regimens for HIV-related opportunistic infections are enumerated in Appendix 3. Dapsone may cause hemolysis in persons with G6PD deficiency. Hemolysis may be severe in certain persons of Mediterranean descent, clinically presenting with marked dyspnea and methemoglobinemia. USPHS guidelines now recommend discontinuing primary prophylaxis for

Self Assessment Answers: Management of HIV Infection

PCP, toxoplasmosis, and *Mycobacterium avium* infections for persons responding to effective antiretroviral treatment with sustained elevations in CD4+ T-cells. Persons with HIV infection and active TB who are appropriately treated for TB do not require continued isoniazid prophylaxis after completion of effective therapy.

Question #6, Answer is D
Antiretroviral therapy is indicated for persons with HIV infection with thrush, any AIDS-defining illness, other serious symptomatic illness associated with HIV, depressed CD4+ T-cells (< 350-500/mm^3), or elevated plasma HIV RNA levels (> 20,000 cps/mL by the polymerase chain reaction. (See Appendix 4) Persons with undetectable or low HIV RNA levels (< 20,000 cps/mL) with borderline depressed CD4+ T cells (350-500/mm^3) should be monitored closely and counseled thoroughly before initiating antiretroviral therapy, since the short term prognosis is excellent off medications, and the long term risks and benefits on medications are uncertain.

Question #7, Answer is C
Indinavir therapy is strongly associated with symptomatic kidney stones and renal insufficiency (independent of kidney stones). All protease inhibitors are associated with lipid abnormalities and hyperglycemia. Pancreatitis is a potentially serious complication of ddI therapy. AZT ordinarily causes a **macrocytic** anemia that is usually well tolerated, but can be severe. Dose escalation of ritonavir reduces gastrointestinal side effects; dose escalation of nevirapine reduces the incidence of rash.

Question #8, Answer is E
The antiretroviral medication abacavir is associated with a hypersensitivity reaction that can be life threatening if the medication is stopped and then restarted. Although uncommon, all nucleoside reverse transcriptase inhibitors (NRTIs) can potentially cause a syndrome of lactic acidosis and hepatic failure; immediate discontinuation of the NRTI is indicated. The dual hepatic metabolism of protease inhibitors and certain drugs (cisapride, terfenadine, and astemizole) can cause cardiac arrhythmias. Most rashes associated with nevirapine are self-limited, but severe exfoliative dermatitis (Stevens-Johnson syndrome) can occur.

Question #9, Answer is E
Specific antiretroviral therapies should be considered for pregnant women in accordance with the most recent DHHS treatment guidelines and in consultation with a physician with experience treating pregnant women with HIV infection. Pregnancy itself does not preclude aggressive treatment for HIV, however, specific treatment regimens are recommended based on their proven efficacy

Self Assessment Answers: Management of HIV Infection

in pregnancy and the risk of teratogenicity. Hydroxyurea and efavirenz should specifically be avoided due to their teratogenic potential. Antiretroviral therapy significantly reduces perinatal transmission of HIV, best documented with AZT therapy. Tuberculosis can be effectively treated despite immunosuppression from HIV infection. Certain HIV co-infected persons may require longer courses of TB treatment, but treatment is usually effective with standard treatment regimens when provided under direct observation in the absence of multi-drug resistance. Rifampin has significant drug interactions with protease inhibitors as well as certain other antiretroviral medications. Treatment of TB in persons with HIV infection on antiretroviral therapy usually requires a nonstandard TB treatment regimen to avoid drug interactions that may render HIV treatment less effective or increase drug toxicities.

Question #10, Answer is C
The risk of acquiring HIV from a single percutaneous exposure is roughly 3 in 1,000 (0.3%), but the risk increases with the depth of the injury, if visible blood was present on the device causing the injury, if the device was previously in a vein or artery, and if the source of the exposure was a person with AIDS. Inmate workers are candidates for emergent antiretroviral post-exposure prophylaxis in accordance with Bureau policy, CDC guidelines and OSHA requirements. Side effects to antiretroviral medications in persons treated for occupational exposures to HIV have been significant and reduced adherence to recommended regimens. HIV antibody testing is indicated at the time of exposure, and at 6 weeks, 12 weeks, and 6 months after the exposure. HIV antibody testing at 12 months is considered optional, unless otherwise clinically indicated.

Question #11, Answer is A
Strict adherence to medication regimens is essential to achieve sustained HIV suppression. HIV RNA levels were reduced to < 500 cps/mL in 81% of studied patients who were > 95% adherent to their antiretroviral regimen; compared to only 24% of studied patients who were 70-80% adherent.

Question #12, Answer is D
The inmate presented with community acquired pneumonia (CAP) commonly caused by *Mycoplasma pneumoniae* (particularly with an interstitial pattern) as well as other pathogens. The inmate was also at risk for AIDS and the associated complications of *Pneumocystis carinii* pneumonia (PCP) and pulmonary tuberculosis which can both mimic CAP. Treatments for CAP and PCP are indicated along with diagnostic procedures to rule out tuberculosis and if possible identify the offending pathogen.