HIV/AIDS UPDATE 2008

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Division of Continuing Medical Education

HIV/AIDS UPDATE

TABLE OF CONTENTS

GENERAL INFORMATION

This self-instructional learning activity is designed for primary care physicians, medical students, residents, interns and other allied healthcare professionals who are involved in HIV patient management and should be of interest to psychologists, nurses, social workers, marriage and family counselors and other health professionals who deal with the HIV patient.

This course fulfills the CME requirement for Florida licensed physicians.

CONTINUING MEDICAL EDUCATION (CME) CREDIT

Upon completion of this self-instructional activity, the participant has the option of taking the post-test to qualify for continuing medical education credits (CME). To apply for CME credits, circle the appropriate response(s) on the answer sheet at the end of this handout and complete the program evaluation form.

Mail the completed post-test and evaluation form to:

Division of CME
University of Miami Miller School of Medicine
P.O. Box 016960 (D23-3)
Miami, FL 33101-6960

Participants must obtain a score of 70% or more, in order to qualify for continuing medical education credit. The Division of Continuing Medical Education will issue a certificate of participation indicating the hours earned.

ACCREDITATION

The University of Miami Leonard M. Miller School of Medicine is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

This activity was planned and produced in accordance to ACCME Essential Areas, Elements and Policies.

Date of original release: November 1, 2001.

CREDIT DESIGNATION

The University of Miami Leonard M. Miller School of Medicine designates this educational activity for a maximum of **2** *AMA PRA Category 1 Credit(s)™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Credit is available for the period of September 1, 2008 to August 31, 2011 upon successful completion of the post-test.

DISCLOSURE AND CONFLICT OF INTEREST RESOLUTION:

All conflicts of interest of any individual(s) in a position to control the content of this CME activity has been identified and resolved prior to this educational activity being provided. Disclosure about provider and faculty relationships, or the lack thereof, will be provided to learners.

FACULTY DISCLOSURE

Drs. Baracco and Griffin have indicated that they have no relevant financial relationships with commercial interests.

LEARNING OBJECTIVES

Upon completion of this self-instructional activity, participants should be able to:

- Accurately diagnose, treat and refer patients with HIV/AIDS or suspected of having HIV/AIDS
- Be knowledgeable of Florida laws specific to this disease
- Implement preventive measures when dealing with patients suspected of having HIV/AIDS

Introduction

According to World Health Organization estimates, approximately 1.3 million people in North America lived with Human Immunodeficiency Virus (HIV) infection at the end of 2007.

The HIV epidemic has deeply affected not only medicine but society itself. A diagnosis of HIV infection has such important medical, psychological, social, and financial implications that the State of Florida has mandated that all practicing physicians in the State receive training about this disease equivalent to 1.0 CME credit as a requirement for initial licensure.

The following pages provide a comprehensive yet concise, up-to-date and easy to read review of the information that a practicing physician of any specialty in the State of Florida should know about this disease.

Pathogenesis and Natural History of HIV Infection

HIV-1 and HIV-2 belong to the *Retroviridae* family of RNA viruses.

After percutaneous or permucosal inoculation, dendritic cells present in the tissue will "capture" the virus through a receptor called DC-SIGN. Virions bound to DC-SIGN are internalized and subsequently displayed on the cell surface after the dendritic cell has matured and migrated to regional lymph nodes where it engages T cells. Once HIV is released, its envelope protein gp120 will recognize and attach to CD4 receptors (and some co-receptors such as CCR5 and CXCR4) on T lymphocytes, and will enter the cell by fusion and endocytosis. Once inside the cell, reverse transcription of the HIV RNA results in the production of a preintegration complex (PIC), which is composed of double-stranded cDNA and a number of genes needed for integration. This provirus will then enter the cell's nucleus and integrate itself to one or multiple chromosomal loci. Integration can result in either latent or transcriptionally active forms of infection. Once

inserted into the cell's chromosome, pro-viral RNA will be transcribed and translated into pro-viral components, which are spliced and assembled at the membrane and released to infect other CD4+ cells.

After a period of 1 – 8 weeks approximately 70% of the newly HIV-infected patients develop a mononucleosis-like illness characterized by fever, myalgias, pharyngitis and generalized non-specific lymphadenopathy. Some patients develop a generalized papulomacular rash, and a few develop hepatitis and aseptic meningitis. This illness is known as the acute retroviral syndrome, or primary HIV infection. It is usually a benign, self-limited illness, though some patients may have a more severe form and seek medical attention. The infection is frequently unrecognized even in those patients who go to their medical provider. The resolution of symptoms coincides with the appearance of specific immunity and seroconversion.

After the acute retroviral syndrome resolves, patients enter a period of clinically silent infection of variable length. These patients are asymptomatic, many don't know they are infected, but they are certainly contagious and may spread the disease to their sexual and parenteral drug partners, and to their offspring. The integrity of the patient's immune system –estimated by quantification of $CD4^+$ T-lymphocytes per unit of blood ("$CD4^+$ count")- deteriorates steadily during this period, at variable rates. The average duration of the asymptomatic phase, in the absence of therapy, is about 8 to 10 years, but can range from as little as 1 year in rare occasions to a "chronic non-progressor" state, by which a small percentage of infected patients maintain the integrity of their immune system throughout the years. The rate of disease progression is determined by a complex interaction between the fitness of the viral strain and the strength of the patient's specific anti-HIV cellular and humoral immunity.

As the $CD4^+$ count drops and approaches 200 cells/mm^3, the first signs of immune deficiency appear. Unexplained weight loss, generalized lymphadenopathy, fatigue,

and oral or vaginal candidiasis are common nonspecific signs of advancing HIV disease. Pneumococcal pneumonia and reactivation of latent tuberculosis are also more common in this stage.

The Acquired Immunodeficiency Syndrome (AIDS) is diagnosed when one of two things occur: a) the $CD4^+$ count drops below 200 cells/mm^3, even though the patient may still be asymptomatic; or b) the patient develops an opportunistic condition (infection or neoplasm) that defines AIDS, regardless of the patient's $CD4^+$ count (see Table 1).

The degree of immunosuppression is a continuum. However, this threshold of 200 $CD4^+$ cells/mm^3 was chosen to provide uniformity for surveillance studies, for disability and social aid, and to assess the need for prophylaxis against certain opportunistic pathogens.

Patients with AIDS are more likely to acquire a variety of diseases that persons with a stronger immune system would not. At this stage, patients frequently develop a hypercatabolic state due to increased levels of cytokines related to their chronic disease. This leads to weight loss, progressive weakness, and often chronic diarrhea. They are also prone to develop *Pneumocystis carinii* pneumonia. This predisposition increases as the $CD4^+$ count declines. Patients with a $CD4^+$ count below 50 cells/mm^3 are at risk of developing disseminated *Mycobacterium avium* infection, cytomegalovirus disease, and progressive multifocal leukoencephalopathy (PML).

The natural history described above has been significantly affected by the introduction of effective antiretroviral therapy. Treatment maintains and even reconstitutes to a great degree the immune system of the majority of patients, and has been shown to prolong their survival and decrease morbidity associated with advancing immunodeficiency.

Epidemiology

As of December 2007 an estimated 33.2 million people worldwide are currently living with HIV; 2.4 million of which acquired the infection in 2007. There were 2.1 million HIV deaths in 2007. Over two thirds (68%, 22.5 million) of all people living with HIV are in sub-Saharan Africa where the adult prevalence is 5%.

There were an estimated 1.3 million people living with HIV in North America in 2007. Updated estimates reveal 46,000 people were newly infected and 22,000 died from HIV/AIDS during 2007. African-Americans are disproportionately affected by this epidemic. They account for 25% of AIDS cases, and 45% of newly infected individuals, but only 12% of the US population.

The prevalence of the disease is increasing steadily, even though the number of new cases has been fairly stable during the last decade, due to an increased survival as a consequence of the use of effective combination antiretroviral therapy.

Ethnic minorities and poorer populations have less access to care, hence benefiting less from the effects of therapy and from prevention efforts, and are overrepresented in the HIV-positive population.

Modes of Transmission

HIV is transmitted through three main routes: sexual, parenteral, and vertical.

1. Sexual

Sexual intercourse is the leading way of transmission of HIV. This form of transmission occurs mainly among high-risk groups, such as men who have sex with men and sex workers. However, the number of cases acquired by heterosexual transmission has risen significantly in recent years and account for a very significant proportion of new infections. In 2006 31% of new HIV infections were attributed to heterosexual transmission.

The risk of sexual transmission is in direct relationship with the amount of trauma and laceration of the recipient's genital mucosa. So, receptive anal intercourse provides the greatest risk, and the rate of transmission from a man to a woman is greater than the opposite. Genital ulcers from co-existing sexually transmitted diseases such as syphilis and Herpes simplex also enhance transmissibility of the HIV virus.

Other factors that influence the risk of sexual transmission of HIV are related to the prevalence of HIV in the patient's environment, the number of sexual partners, the exchange of sex for drugs or money, and the viral load of the infecting partner.

2. Parenteral

Before 1985, at least 50% of the approximately 16,000 patients with hemophilia in the US and an additional 12,000 blood-transfusion recipients were infected with HIV. Hemophiliacs were at a particularly high risk because a single dose of cryoprecipitate contained products from between 1,000 and 20,000 donors. Today the use of recombinant clotting factors, screening questionnaires, and tests performed to ensure that the blood transfused does not carry an infectious agent make HIV transmission through blood and blood products a very rare event in the US. Each unit of blood undergoes at least ten different tests, as compared to only two (hepatitis B and syphilis) required in 1981.

Users of illicit parenteral drugs continue to account for a large number of infections. Needle-sharing and dilution of drug with blood are common practices, as well as engagement in high-risk sexual practices like exchanging sex for drugs and money. Infection with other blood borne pathogens, such as hepatitis B and C viruses, are also common in this group. Due to the repetitive nature of their potential exposure, it is very difficult to quantify the efficiency of this kind of transmission, but it is likely to be high.

3. Vertical transmission

Vertical (mother to child) transmission is the number one cause of HIV infection in children. It occurs mostly during the perinatal period, and during breastfeeding. Several factors have been associated to an increased risk of transmission, and most have to do with the maternal viral load, the exposure of the newborn to maternal blood during delivery, and to breastfeeding. Good prenatal care, adequate antiretroviral therapy to the mother and child, cesarean section, and not breastfeeding are all associated with decreased transmission of HIV. Even in mothers without chronic therapy for HIV and without prenatal care, antiretroviral agents given through labor and delivery, together with early treatment of the newborn, decrease significantly the risk of transmission.

Diagnosis

The CDC updated its guidelines for HIV Testing in 2006 to reflect the changing demographics of HIV infection in the USA, particularly increasing proportions of heterosexual transmission and women comprising new HIV infections. Routine voluntary HIV screening is recommended as a part of standard medical care. This includes incorporation of screening in acute care settings such as Emergency Departments. These recommendations, however, have not yet been incorporated into Florida Statute. A summary of the updated recommendations is as follows:

1. Routine screening for HIV infection should be performed for patients aged between 13-64, unless the documented HIV prevalence in the community is < 0.1 %.
2. Patients seeking treatment for STDs and at subsequent visits for a new complaint.
3. Patients initiating treatment for TB.

In addition, new recommendations for repeat screening include annual testing for high risk groups, and both prospective partners prior to initiation of a new sexual relationship.

Florida law carefully structures the manner in which health care providers may obtain HIV tests. The following paragraphs outline the minimal statutory requirements for performing HIV testing.

The process of testing a person for HIV involves five steps:

1. Risk assessment

The evaluation of a particular patient's risk for HIV infection should be an integral part of the routine primary health care. Patients should be made comfortable and should be assured of the confidentiality of their answers, and the physician has to approach him or her in an objective, non-judgmental manner, devoid of demographic or sociocultural prejudice (Table 2). The provider should elicit information about high-risk sexual behavior and lifestyle, illicit drug use, and medical conditions that may be associated with an increased incidence of HIV infection. Counseling and testing is then offered as appropriate (Table 3).

According to Florida law, all pregnant women should be offered an HIV test. Treatment for her and her baby should be available if the woman tests positive. Patients who refuse testing need to sign a "Statement of Objection to HIV testing", available in English, Spanish, and Creole at http://www.doh.state.fl.us/disease_ctrl/aids/testing/testing.html. A woman who tests positive, in addition to the indicated medical and psychological treatment, can be referred to the Healthy Start Care Coordination System (for information, call 1-800-FLA-AIDS).

2. Pre-test counseling

Pre-test counseling is no longer required by Florida law, except in the case of a provider who attends a pregnant woman for conditions related to her pregnancy, but it is strongly encouraged. It may be done through written material. It should include information

about the purpose of the HIV test; the indications for testing (medical and/or high risk); the possible need for retesting; information on how to avoid contracting and transmitting HIV infection; the potential social, medical, and economic effects of a positive test result; and, options for eliminating/reducing risk behavior. It should also state the availability of support services for those awaiting test results, and the provider should schedule a specific date for receiving test results. The information should be transmitted in a face to face format in a manner appropriate to the client's culture, language, gender and age.

3. Informed consent

An informed consent must ALWAYS be obtained. The limited exceptions to obtaining informed consent are outlined in Table 4. The informed consent does not need to be in writing, provided there is adequate documentation in the chart that the test was explained and informed consent was obtained, except when HIV testing is done prior to first donation of blood or organs, and when it is done for insurance purposes. However, WRITTEN INFORMED CONSENT IS STRONGLY ENCOURAGED. A model informed consent form can be downloaded from

http://www.doh.state.fl.us/disease_ctrl/aids/testing/testing.html

The following information has to be explained, as a minimum:

- Right to confidential treatment of the information to the extent provided by law. Persons with knowledge of an individual's HIV test result have legal obligations to protect this information from unauthorized disclosure (Table 5).
- An HIV test is used to determine if an individual is infected with the virus that causes AIDS.
- The potential uses and limitations of the test.
- The procedures to be followed, including pre- and post-test counseling.
- That HIV testing is voluntary, and consent can be withdrawn at any time prior to testing.

Patients should be informed that positive test results will be reported to the county health department for follow-up activities, and they must also be given information about the availability of anonymous testing. A list of anonymous test sites is available at each county health department.

4. Testing

Testing for HIV is performed by looking for HIV-specific antibodies in the patient's blood. The usual screening test is by the ELISA (Enzyme-linked immunosorbent assay) method. Even though it is a very specific method, a positive result must always be confirmed by a second test; Western Blot assay is the most widely used. It is unlawful to disclose to the patient unconfirmed positive ELISA assays, except when decisions about medical care or treatment cannot await the results of confirmatory testing. Justification for the use of preliminary test results must be documented in the medical record by the health care provider who ordered the test.

There are certain circumstances, such as screening a baby born to an HIV-positive mother, or diagnosing acute retroviral syndrome, in which antibody testing is not reliable. In those situations, the diagnosis should be made by looking for viral particles, such as RNA, pro-viral DNA (RT-PCR or bDNA assays), or proteins (p24 antigen levels).

5. Post-test counseling

All reasonable efforts must be made to notify the test subject of his or her test result. Post-test counseling should be offered to all test subjects and should be based on the test result and the individual's needs as determined during the risk assessment.

In the case of a hospital emergency department, detention facility, or other facility where the test subject has been released before being notified of positive test results, informing the county health department fulfills this responsibility.

When test subjects are given their test results, Florida law requires that, at a minimum, the following information is provided:

- For people with a positive test result, information on preventing transmission of HIV, the availability of appropriate medical and support services, and the importance of notifying sex and/or needle-sharing partners. Providers must make a good faith effort to ensure that spouses and former spouses (from the past ten years) of HIV-infected persons are notified that they may have been exposed to HIV infection. Each test subject shall also be made aware of the availability of a county health department confidential partner notification program.
- For people with a negative test result, information on preventing the transmission of HIV, if appropriate.

Clinical Management

Once diagnosed, HIV-positive patients should be evaluated by a healthcare provider experienced in the care of these patients. The assessment will include establishing the stage of their disease, concomitant conditions like tuberculosis, latent infections such as Toxoplasma, other sexually transmitted diseases, and hepatitis B and C. In addition an assessment of overall medical health should be made, include evaluation of pre-existing chronic conditions such as Diabetes, coronary heart disease, chronic renal of liver disease and dyslipidemia; conditions that may be effected by antiretroviral therapy. The patient will receive appropriate immunizations and prophylactic medication. A multidisciplinary approach is preferred, with the intervention of psychologists, clinical pharmacists, clinical educators, nutritionists, and social workers.

Antiretroviral therapy is available in the form of a multi-drug combination regimen referred to as combination antiretroviral therapy or "HAART" (Highly-Active AntiRetroviral Therapy). The goals of therapy are to achieve maximal and durable suppression of viral

load, restoration or preservation of immunologic function, improvement in quality of life, and reduction of HIV-related morbidity and mortality. These goals are achieved by maximizing adherence to the antiretroviral regimen, and using drug-resistance testing in selected clinical settings. How the available drugs are sequenced and the preservation of future treatment options are also important tools.

Several different classes of antiretroviral medications exist. Classification is based on mechanisms of action which selectively inhibit HIV replication in variable stages of the HIV lifecycle. In order to maximize the chance of obtaining significant virilogical suppression a treatment regimen should contain agents that fall within at least two different treatment classes. Commonly used agents target the HIV specific enzyme reverse transcriptase- these may be nucleoside analogues referred to as nucleoside reverse transcriptase inhibitors (NRTI) or drugs that inhibit reverse transcriptase by a different mechanism, i.e. non nucleoside reverse transcriptase Inhibitors (NNRTI). Other pathways targeted include inhibition of the function of Protease and Integrase enzymes- Protease Inhibitors (PIs) and Integrase Inhibitors respectively. Other agents target the binding, fusion and entry of HIV into the target cell- Entry inhibitors (Table 6). A typical starting combination antiretroviral regimen consists of 2 nucleoside reverse-transcriptase inhibitors (NRTI), and either a non- nucleoside reverse-transcriptase inhibitors (NNRTI) or a protease inhibitor (PI). Ritonavir (a PI) is often used in combination with other PIs to boost the serum level of the other PI by inhibiting its metabolism by the cytochrome P450 enzyme system. These regimens should be designed by a practitioner experienced in the treatment of patients infected with HIV.

There has been significant discussion about the best time to start ART in an HIV-positive patient. There is no doubt that ART is beneficial in patients with AIDS or symptoms related to immunosuppression and these patients should be offered therapy. For asymptomatic

patients with $CD4^+$ count greater than 200 cells/mm^3, the benefit is less clear. The decision to initiate treatment in these patients should take into account the readiness of the patient for treatment, consideration of the prognosis for disease-free survival as determined by baseline $CD4^+$ T cell count and viral load levels, and assessment of the risk and potential benefits associated with initiating ART. Antiretroviral therapy should also be offered to patients with a $CD4^+$ count of less than 350 cells/mm^3. The potential benefits of ART in asymptomatic patients with fairly intact immune systems ($CD4^+$ count >350), versus the drawbacks of therapy, such as toxicity -including dyslipidemia and accelerated atherosclerosis-, adherence, emergence of resistance, cost, etc., are being debated. Newer data is emerging, however, suggesting that initiating treatment at higher CD4 thresholds may provide long term benefit, though this has yet to be incorporated into current practice guidelines.

Special groups of patients that benefit from treatment regardless of CD4 level include pregnant women- whereby the risk of vertical transmission is reduced; those with HIV induced kidney damage (HIV nephropathy), and Hepatitis B/HIV co-infected patients that require therapy for Hepatitis B.

Prophylaxis of opportunistic infections is an important element of the care of AIDS patients. Thresholds usually defined by arbitrary CD4 counts are used to instigate prophylactic antibiotic therapy to reduce the incidence of opportunistic infections. These include: Pneumocystic jeroveci (a common cause of pneumonia when CD4 count is under 200), Toxoplasma gondii (a parasite associated with brain lesions, most often occurring with CD4 counts of under 100), Mycobacterium Avium Complex (MAC)- a group of atypical Mycobacteria that can cause disseminated disease in the advanced AIDS host (CD4 usually under 50).

Prevention

Preventing new HIV infections is a priority in any HIV control program. There needs to be a strong political and resource commitment from the government and the community for this purpose. Education, support, access to healthcare and effective treatment all must be included in a successful program.

Sexual education is an important component, and should be always provided at an age-appropriate level. Physicians need to teach their patients to avoid high-risk sexual behavior and promote safe sex practices. Patients who inject illicit drugs should also be taught about the risks of needle-sharing. Healthcare workers and any person with occupational exposure to blood borne pathogens need to be proficient in using standard infection control precautions.

Other components of a prevention program include extensive HIV testing programs and treatment of HIV infection and other STDs in the community.

HIV and the Healthcare Worker

As of December, 2002 there were 57 documented cases of occupationally acquired HIV infection by healthcare personnel as well as a further 139 possible cases.

Standard precautions are generally adequate for the care of patients with HIV. They include hand washing before and after each patient contact and the use of gloves. Other personal protective equipment, such as gowns, eye shields, and masks, are only necessary when exposure to blood or other body fluids is anticipated.

Healthcare workers may occasionally have an accidental parenteral exposure to HIV. It is estimated that roughly 500,000 percutaneous blood exposures occur each year among hospital-based healthcare workers in the United States. Of these, approximately 5000 occur with patients that have HIV infection. The average risk of HIV transmission after percutaneous exposure to HIV-infected blood is approximately 0.3%, or 1 case in

300+ exposures. This risk will vary depending on the depth of the wound, the amount of blood present on the sharp instrument, the use of gloves, and the viral load of the patient. When the exposed area is a mucous membrane or non-intact skin, the risk of HIV transmission is even lower. It is calculated in 0.09% of exposures, or 1 in 1100 accidents. HIV transmission from exposure of infected blood to intact skin has not been documented, and the risk is believed to be extremely small, if any.

After a significant exposure, the wound or mucous membrane should be flushed immediately with copious amounts of water. Each institution has specific protocols to follow after an exposure, and healthcare workers should be familiar with them. It usually entails reporting immediately to the institution's employee health office, infection control office, or emergency department. There, the exposed person will be evaluated, screened, counseled, and prophylaxis offered if appropriate. Informed consent should be obtained from the source of the exposure, if known, to be screened for blood borne pathogens, including HIV, hepatitis B, and hepatitis C infection. If prophylaxis is offered according to the institution's protocol, and the employee accepts to take it, it should be taken as soon as possible, preferably within 2 hours of the exposure. In 2008 a legislative bill was passed in Florida that permits testing of existing blood without consent when a member of medical personnel is exposed and consent cannot be obtained in the timeframe necessary to conduct a test and start prophylactic treatment.

SELECTED REFERENCES

World Health Organization. AIDS Epidemic Update 2008.

http://www.unaids.org/wad2004/report.html

Greene WC, Peterlin BM. Charting HIV's remarkable voyage through the cell: Basic science as a passport to future therapy. *Nature Medicine* 2002; 8(7):673-80

Steinbrook R. Beyond Barcelona – The global response to HIV. *New England Journal of Medicine* 2002; 347(8): 553-4

U.S. Preventive Services Task Force. Screening for HIV: Recommendation Statement. *Ann Intern Med.* 2005;143:32-37.

Centers for Disease Control and Prevention. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Post exposure Prophylaxis. *MMWR* 2001; 50 (RR-11)

Aberg JA et al. Primary Care Guidelines for the Management of Persons Infected with Human Immunodeficiency Virus: Recommendations of the HIV Medicine Association of the Infectious Diseases Society of America. *Clinical Infectious Diseases* 2004; 39:609–29

Bureau of HIV/AIDS. Florida Department of Health.

http://www.doh.state.fl.us/disease_ctrl/aids/legal/legal.html

U.S. Department of Health and Human Services. HIV/AIDS Treatment Information Service website http://www.hivatis.org

Table 1. Conditions included in the 1993 AIDS Surveillance Case Definition

- Candidiasis of bronchi, trachea, or lungs
- Candidiasis, esophageal
- Cervical cancer, invasive
- Coccidioidomycosis, disseminated or extrapulmonary
- Cryptococcosis, extrapulmonary
- Cryptosporidiosis, chronic intestinal (greater than 1 month's duration)
- Cytomegalovirus disease (other than liver, spleen, or nodes)
- Cytomegalovirus retinitis (with loss of vision)
- Encephalopathy, HIV-related
- Herpes simplex: chronic ulcer(s) (greater than 1 month's duration); or bronchitis, pneumonitis, or esophagitis
- Histoplasmosis, disseminated or extrapulmonary
- Isosporiasis, chronic intestinal (greater than 1 month's duration)
- Kaposi's sarcoma
- Lymphoma, Burkitt's (or equivalent term)
- Lymphoma, immunoblastic (or equivalent term)
- Lymphoma, primary, of brain
- Mycobacterium avium complex or M. kansasii, disseminated or extrapulmonary
- Mycobacterium tuberculosis, any site (pulmonary or extrapulmonary)
- Mycobacterium, other species or unidentified species, disseminated or extrapulmonary
- Pneumocystis jeroveci pneumonia
- Pneumonia, recurrent
- Progressive multifocal leukoencephalopathy
- Salmonella septicemia, recurrent
- Toxoplasmosis of brain
- Wasting syndrome due to HIV

From: Centers for Disease Control and Prevention. 1993 Revised Classification System for HIV Infection and Expanded Surveillance Case Definition for AIDS Among Adolescents and Adults. *Morbidity and Mortality Weekly Report* 1992; 41(RR-17)

Table 2. Criteria to Determine an Individual's Risk for HIV Infection

- Sexual behavior
- Substance use/abuse
- Needle sharing
- Occupational exposure
- Blood/blood products/transplants
- Partners at risk for HIV
- History of STDs
- Child of woman with HIV/AIDS
- Victim of sexual assault/domestic violence
- Sex for drugs/money

From: Bureau of HIV/AIDS, Florida Department of Health.

http://www.doh.state.fl.us/disease_ctrl/aids/legal/protocols.html. Accessed 08/28/2008

Table 3. Persons who should be tested for HIV Infection

- Persons with high-risk behavior
    - Men who have sex with men
    - Injection drug users
    - Persons with multiple sex partners
    - Persons who have exchanged money or drugs for sex
    - Persons who have had sexual contact with an HIV-positive person or a person at risk for HIV infection
- Persons who request testing, regardless of risk
- Persons with certain medical conditions
    - AIDS-defining illness
    - Oral candidiasis
    - Generalized unexplained lymphadenopathy
    - Symptoms consistent with acute retroviral syndrome
    - Any sexually transmitted disease
    - Tuberculosis
    - Pregnancy
    - Other (e.g., pneumonia, herpes zoster, recurrent vulvovaginal candidiasis, seborrheic dermatitis, new-onset psoriasis, or oral hairy leukoplakia)
- Persons who have been sexually assaulted
- Persons who have had occupational exposures

From: **Aberg JA et al**. Primary Care Guidelines for the Management of Persons Infected with Human Immunodeficiency Virus: Recommendations of the HIV Medicine Association of the Infectious Diseases Society of America. *Clinical Infectious Diseases* 2004; 39:609–29

Table 4. Situations in Which Informed Consent for HIV testing is not required

- When testing for STDs is required by federal or state law
    - Persons convicted of prostitution
    - Prior to release of inmates from prison
    - Medical examiner
- Screening of blood, plasma, organs
- Bona fide medical emergencies, patient unable to consent. Must be clearly supported by documentation in the medical record.
- When obtaining consent would be detrimental to the patient, and test results are necessary to provide appropriate care to the patient
- HIV test as part of an autopsy
- Victim's request in prosecution of sexual battery
- HIV mandated by court order
- For epidemiological research, if identity of the testee remains anonymous
- When human tissue is collected lawfully for corneal removal or enucleation of the eyes
- After occupational exposure, when blood is available, from a previous draw and only after the patient has refused to give a sample or cannot be located.
- Occupational exposure during a medical emergency outside the hospitalMedically-indicated HIV testing in an infant when a parent cannot be contacted to provide consentHIV testing conducted to monitor the clinical progress of a patient previously diagnosed HIV positive.
- Repeated HIV testing conducted to monitor possible conversion from an exposure

Summarized from: Florida Department of Health. 2008 Florida statutes s. 381.004 (3)(h), F.S. The whole statute should be reviewed for complete information and procedures. http://www.leg.state.fl.us

Table 5. Confidentiality of HIV Test Results

Any person or institution shall comply with the confidentiality provisions of the law in administering an HIV test, protecting the identity of the test subject, and managing records which contain laboratory reports of HIV test results or any report or notation of a laboratory report of an HIV test

No person or institution shall disclose the identity of a test subject or his/her HIV test results, except to the following persons:

- The subject of the test
- Any person designated in a legally effective release
- Any medical personnel who experience a significant exposure during the course of employment or in the performance of duties, or any non-medical personnel who experience a significant exposure while providing emergency assistance
- Any employee of an authorized health care facility, on a "need to know" basis for the performance of his or her duties
- Health care providers involved in the care of a test subject consulting among themselves to determine diagnosis or treatment of the patient.
- The Department of Health
- A health facility or provider which procures, processes, distributes, or uses human body parts from a deceased person or semen for artificial insemination
- Hospital committees for purposes of program monitoring, program evaluation, or service reviews
- Authorized medical or epidemiological researchers
- Those persons authorized under Section 796.08(3), F.S., to receive HIV test results of convicted prostitutes
- The victim of a criminal offense involving transmission of body fluids shall, upon request, obtain the HIV test results of the person charged or convicted of the crime

- In accordance with specific circumstances established in Section 455.674, F.S., a practitioner regulated through the Division of Medical Quality Assurance within the Department of Health can disclose the identity of an HIV positive patient to the patient's sex or needle-sharing partner. Any notification of a sex or needle-sharing partner shall be done in accordance with the "Partner Notification Protocol for Practitioners", dated March 1999
- Employees of the department, child placing or child-caring agencies, or of licensed family foster homes who are directly involved in the placement, care, control, or custody of a test subject and have a need to know such information; the adoptive parents of the test subject; or the adult custodian, adult relative or other person who is responsible for the child's welfare if the parent or legal guardian cannot be located
- Employees of residential facilities or community-based care programs licensed under Chapter 393, F.S., for developmentally disabled persons if the employees are directly involved in the care, control, or custody of such test subject and have a need to know such information.
- A person allowed access by a court order
- A person allowed access by order of a judge of compensation claims of the Division of Workers' Compensation of the Department of Labor and Employment Security.

Adapted from: Rule 64D-2.003, Florida Administrative Code 2008. The whole rule should be reviewed for complete information and procedures.
https://www.flrules.org/Gateway/View_notice.asp?id=2517458

Table 6. Drugs Used In the Treatment of HIV Infection

NRTI	**NNRTI**	**Protease Inhibitors**	**Integrase Inhibitors**	**Fusion/Entry Inhibitors**
Zidovudine	Efavirenz	Saquinavir	Raltegravir	Enfuvirtide
Didanosine	Nevirapine	Ritonavir		Maraviroc
Stavudine	Delaviridine	Indinavir		
Lamivudine	Etravirine	Nelfinavir		
Abacavir		Amprenavir		
Tenofovir		Fosamprenavir		
Emtricitabine		Lopinavir		
		Atazanavir		
		Tipranavir		
		Darunavir		

Drugs approved by the FDA as of September, 2008

Post Test

For the following multiple-choice questions, there is only one correct answer.

1. Which of the following interventions does NOT decrease the rate of vertical transmission of HIV:
    a. Breastfeeding
    b. Antiretroviral therapy to the mother
    c. Cesarean section
    d. Antiretroviral treatment to the newborn

2. Which of the following statements about testing for HIV infection is NOT correct:
    a. Face-to-face pre-test counseling is mandated by Florida law
    b. The usual screening test is done by the ELISA method
    c. Obtaining informed consent is the most important step in the testing process, and should be done always, except in the few situations allowed by law.
    d. Post-test counseling should be done, regardless of the result of the test.

3. Which is NOT a component of an HIV-prevention campaign
    a. Sexual education
    b. Screening for STDs
    c. Clean-needle programs
    d. Immunizations

4. What is the average risk of HIV transmission from a percutaneous occupational exposure to HIV-infected blood?
    a. 1:3
    b. 1:30
    c. 1:300
    d. 1:3000

5. The prevalence of HIV-positive persons in the US is:
    a. Stable
    b. Rising steadily
    c. Decreasing steadily

6. Which of the following conditions, in an HIV-positive patient, does NOT define AIDS:
    a. Pneumocystis carinii pneumonia
    b. Oral candidiasis
    c. Uterine cervical cancer
    d. Recurrent pneumococcal pneumonia
    e. CD4 count less than 200 cells/mm^3

7. Which of the following classes of medications is NOT used to treat HIV?
    a. Nucleoside reverse transcriptase inhibitors
    b. Integrase Inhibitors
    c. Interferons
    d. Protease Inhibitors
    e. Fusion Inhibitors

For the following questions, please answer True (T) or False (F)

8. Patients with HIV infection have an increased risk of reactivating latent tuberculosis only when they are profoundly immunosuppressed (CD4 <50 cells/mm^3)

9. A multidisciplinary approach, involving physicians, psychologists, pharmacists, educators, nutritionists, and social workers, is ideal for the care of an HIV-positive patient.

10. All pregnant women, regardless of other risk factors, should be offered HIV testing

EVALUATION

HIV/AIDS UPDATE 2008

Your comments are extremely valuable in assisting us to plan programs that will better serve you. Please complete and return this evaluation form along with your post-test answers and fee to receive credit.

MAIL TO: Division of Continuing Medical Education
University of Miami Miller School of Medicine
P.O. Box 016960 (D23-3)
Miami, FL 33101-6960

Evaluate this self-instructional activity on the following criteria:
(please circle one answer in each of the following categories)

Overall Evaluation:
5 = Excellent
4 = Above Average
3 = Average
2 = Below Average
1 = Poor

Content Level:
3 = Advanced
2 = Intermediate
1 = Basic

Please rate the following (5 = Strongly Agree … 1 = Strongly Disagree)

Upon completion of this self-study, I am able to:

1. Accurately diagnose, treat and refer patients with HIV/AIDS or suspected of having HIV/AIDS	**5**	**4**	**3**	**2**	**1**
2. Explain the Florida laws specific to this disease	**5**	**4**	**3**	**2**	**1**
3. Implement preventive measures when dealing with patients suspected of having HIV/AIDS	**5**	**4**	**3**	**2**	**1**

Would you recommend this self-instructional activity to a colleague? ____Yes ____No

Will you make any changes in your professional practice as a result of this CME study? ____Yes ____No

Was this activity fair, balanced and free from commercial bias? ____Yes ____No

Comments:

Complete the test on the reverse side to receive credit and fax to 305-243-5613.

Post-Test Answer Sheet/Credit Recording Form
HIV/AIDS Update 2008

Name: _____Degree: _____

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Specialty: _____ Last 4 digits of Social Security #: _____
(Last 4 digits ONLY for recording credit)

Circle the correct answers below and mail this form to the address indicated on the evaluation page to request credit. A score of 70% of higher must be obtained on the Post-Test in order to receive credit.

1.	A	B	C	D	**6.**	A	B	C	D	E
2.	A	B	C	D	**7.**	A	B	C	D	E
3.	A	B	C	D	**8.**	T	F			
4.	A	B	C	D	**9.**	T	F			
5.	A	B	C	D	**10.**	T	F			

CERTIFY COURSE COMPLETION

❒ I certify that I have completed the HIV/AIDS Update program and post-test and wish to receive credit.

Indicate the total amount of time you spent completing this educational activity: _____
A maximum of **2** *AMA PRA Category 1 Credits*™ will be awarded for completion of the program.

Signature: _____ Date: _____

TUITION: $50.00

❒ Check enclosed in the amount of $50.00 (USD) made payable to **UM, Division of CME**

❒ Charge my recording fee in the amount of $50.00 to the following credit card:
❒ MasterCard® ❒ Visa® ❒ Discover®

Card Number:_____

Expiration Date:_____CVV # (3 digits on back of card) _____

Name on Card: _____

Authorized Signature: _____