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NJ Court Rules: Provider Responsibility in HIV Testing

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Continuing Education Section:

Features

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Patients Have A Right to Know: A Landmark Case

Brenda J. Christian, MEd, PA-C
Quality Specialist
UMDNJ-CCOE-Division of AIDS Education

The Court Ruling

On August 10, 2006, in a landmark appeal, the Superior Court of New Jersey, Appellate Division, ruled that "a health care provider, who orders an HIV test for a patient, has a duty to take reasonable measures to notify that patient of the results of the test."[1] Furthermore, it affirmed that both the hospital and the attending physician, by virtue of their failure to inform the patient of his test results, may be sued by any person that patient infects.

A Patient with a Mysterious Syndrome is Hospitalized

On August 5, 1994, a twenty-nine year old male (C.W.) presented to the emergency department of Cooper Hospital, Camden, complaining of progressive lethargy, confusion, and mental status changes. His medical history was significant only for marijuana abuse, and a hospital drug-screening test confirmed that no other illicit drugs were present. With a working diagnosis of encephalitis, r/o meningitis, C.W. was admitted to the intensive care unit and infectious disease and neurology consults were ordered. Two days after his admission, a resident assigned to C.W.'s care obtained consent for HIV testing from the patient's mother, and the test was performed. C.W.'s condition subsequently improved. He was transferred out of ICU and continued his care in the medical unit until his discharge on August 10, 1994. His discharge diagnosis was toxic encephalopathy secondary to marijuana abuse. C.W. was instructed to avoid strenuous exercise, and to report to his personal physician should he develop any signs of change in mental status. His discharge instructions made no mention of his HIV test and he was not given an appointment to return for follow-up.

Continued on next page

What can health care providers do to avoid missing opportunities and assure that others do not fall between the cracks?

- ☑ ***Every hospital needs to have procedures in place to notify the patient that he or she is infected with HIV.***
- ☑ ***If the hospital is unable to inform the patient, it should have policies and procedures in place to inform the NJDHSS-DHAS Notification Assistance Program (NAP):***
  (877) 356-8312 or
  (973) 648-7500
- ☑ ***Every hospital must fully complete the HIV/AIDS reporting form including the boxes indicating if the patient has received his or her results, and if NAP should do the contact follow-up.***

The Test Results Come In

On August 13, 1994, three days after C.W.'s discharge, Cooper Hospital laboratory received his test results: C.W. had tested positive for HIV. Cooper Hospital laboratory protocol for test results received from outside laboratories, at that time, dictated notifying the attending physician of the report and maintaining confidentiality by recording HIV test results in a designated notebook. There was no existing protocol to ensure that C.W. received his test results, or that they were sent to the state health department.

The Patient Receives a Diagnosis ... 8 Years Later

In April 2002, after numerous complaints of abdominal pain, his personal physician referred C.W. to a gastroenterologist. Endoscopic findings revealed that C.W. suffered from severe esophageal candidiasis and laboratory findings confirmed that C.W. had AIDS. C.W.'s girlfriend, and mother of his then six-year old daughter, consented to HIV testing at that time. Her results were positive. Their daughter tested negative.

The Consequences of Missed Diagnosis

Because C.W. was never informed of his test results, he did not receive the care and treatment that could have kept his HIV infection from progressing to AIDS. Because C.W. did not receive his test results and had no knowledge of his HIV-positive status, he engaged in unprotected sex, unknowingly exposing his sexual partner to HIV, and he fathered a daughter whom he may never see into adulthood. Because C.W. was not informed of his test results, he was denied the opportunity to make responsible choices which may have spared his partner from acquiring HIV/AIDS, and may have prevented them from creating a child who could either acquire the disease or be left an orphan.

Who Is Responsible?

So whose responsibility was it to inform C.W. of his test results? And who is liable for the physical and emotional pain and suffering C.W. and his partner and daughter continue to endure because they were not informed of his HIV status? From the time of the HIV test to the time C.W. left the hospital, many health care professionals were involved in his care: the resident who ordered the test, the attending physicians on the intensive care unit and the medical floor, the consulting infectious disease specialist, the director of the pathology department (laboratory), the physician who prepared the discharge summary, and the nurse who delivered the discharge instructions. In this case, none had official responsibility for assuring that he was given the results, whether directly or through supervisees. No protocol existed for providing guidance on treatment and on reducing the risk of transmission to others. Consequently, the patient learned of his HIV infection when diagnosed with an opportunistic infection indicating the diagnosis of AIDS.

Hospital Protocol

Hospital protocol must establish a step-by-step plan for the acquisition and dissemination of HIV Ab test results received after a patient has been discharged from the hospital. The plan must identify how the results are logged, who should be notified when the results are received, what course of action should be taken if that individual or individuals fail to retrieve the results, and who is responsible for notifying the state when results are positive. Additionally, policies and procedures must include instructions for notifying the New Jersey Department of Health and Senior Services-Division of HIV/AIDS Services (NJDHSS-DHAS) Notification Assistance Program (NAP) if assistance is needed in locating the patient, at (877) 356-8312 or (973) 648-7500.

Private Offices, Community Health Clinics

This case addresses hospital responsibility in informing patients of HIV test results, but should also alert private physicians, and community health clinics of the need for similar protocols. Policies and procedures must address the steps to be taken to locate the patient when positive results are received. Health care providers must be made aware of the Notification Assistance Program (NAP) and utilize its services when appropriate. NJDHSS-DHAS has provided information about NAP to all physicians who have reported a case of HIV/AIDS within the last 3 years. As New Jersey has the fifth largest number of AIDS cases in the country, **all** health care providers should expect that they are seeing or will see patients with HIV/AIDS, and be aware of their responsibilities and resources for following up on positive HIV antibody test results.

[1] Superior Court Of New Jersey, Appellate Division, Docket No. A-6100-04t2: *C.W., as Father of J.W., a Minor and in His Own Right, and E.Y., as Mother of J.W., a Minor And In Her Own Right., Plaintiffs-Appellants, V. The Cooper Health System, D/B/A Cooper Hospital/ University Medical Center, Edison Catalano, MD And Anthony Sherman, MD.*

Notification Assistance Program (NAP)

The New Jersey Department of Health and Senior Services - Division of HIV/AIDS Services (NJDHSS-DHAS) can collaborate with health care providers to follow-up on HIV-infected persons. The Notification Assistance Program (NAP) is a statewide service of the NJDHSS-DHAS designed to provide follow-up services to health care providers for HIV-positive patients who do not return for test results, counseling, and medical referrals.

The NAP can contact the sexual or needle sharing partners of patients to provide confidential counseling and testing. The NAP is a voluntary, confidential service through which no partners will become aware of the source of the referral or the identity of the HIV-positive individual naming them. Health care providers interested in using NAP services for locating contacts or providing follow-up for their HIV-positive patients can call the NAP at: **(877) 356-8312** or **(973) 648-7500**.

Missed Opportunities to Prevent Viral Hepatitis

Guest Editorial:
Andrew de la Torre, MD

The ability to effectively control viral replication in HIV-infected patients has dramatically improved with HAART. As a result, AIDS has evolved from a fatal disease to a controllable chronic illness. Asymptomatic long-term HIV survivorship has increased substantially. However, with increased longevity, people living with HIV are suffering another wave of chronic viral illness that may prove more deadly than HIV.[1]

HIV-HCV and HIV-HBV co-infection rates are about 30-60% and 10-30% respectively. In the United States, HIV, HCV and HBV are largely a result of recreational intravenous drug use (IDU) and/or associated with sexual practices. HIV, HCV and HBV share similar modes of transmission.[2] Thus, when a person is known to be HIV-positive or meets screening criteria for HIV they also should be tested for HBV and HCV for the following reasons:

- Any patient with HIV infection who has not been infected with HBV can avoid this infection by being immunized with HBV vaccine.
- Cirrhosis and liver failure are quickly becoming major causes of death among long-term survivors as HIV promotes a more rapid progression of HCV and HBV related liver damage.
- The risk of liver cancer dramatically increases with cHBV and/or cHCV/cirr.
- Several agents within the HAART regimens are hepato-toxic and can exacerbate liver damage.
- Treatment of chronic viral hepatitis before moderate or severe hepatic fibrosis onset improves tolerability of hepatitis anti-viral treatment, ultimately translating to improved viral eradication.

For every person infected with HIV, there are 4-5 people infected with either chronic hepatitis B or C. Up to 4 million people in the United States are chronically infected with hepatitis C (cHCV) and 1.25 million people with chronic hepatitis B (cHBV). [3, 4] However, these numbers are underestimated, due to the exclusion of prison and homeless populations that are known to have disproportionately high rates of chronic viral hepatitis infection.[5]

The Center for Disease Control estimates the number of people with long-term complications from hepatitis C alone may quadruple by 2015-2020.[6] Long-term complications from chronic viral hepatitis include cirrhosis, liver failure and hepatocellular cancer (HCC). HCC is the most rapidly increasing cancer in the United States and is highly lethal because it is mostly diagnosed at a late and untreatable stage. The risk for developing liver cancer per year is 4-10% for cHBV and 2-8% for cHCV with cirrhosis (cHCV/cirr) respectively. Of people who develop hepatocellular cancer, over 60% are associated with chronic viral hepatitis (47% from HCVcirr, 15% from HBV).[7] Targeted HCC screening in those afflicted with chronic viral hepatitis results in diagnosis at an earlier stage and improves survival.[8]

Anti-viral treatment consisting of pegylated interferon and ribavirin can eradicate the HCV virus in 50% of people with genotypes 1 and 4, and 80% of people with genotypes 2 and 3.[9] Nucleoside/nucleotide analogues and interferon are approved therapies for cHBV, these include: lamivudine, adefovir, entecavir, and pegylated interferon.[10] However, aside from anti-viral treatment, liver disease progression and HCC risk can also be decreased by cessation of alcohol use and activities that risk added infection with hepatitis A or B infection. Vaccination is essential against hepatitis A and B infection in those with chronic HCV, and vaccination against hepatitis A in those with chronic HBV, to prevent further liver damage and possible death in those with underlying liver damage.

In New Jersey, chronic viral hepatitis accounts for 55-57% of people in need of a liver transplant, compared to 35% nationwide. Between 2010-2015, chronic viral hepatitis related complications will increase the number of New Jersey residents in need of liver transplant by 50-75%. Eighty percent of people receiving a liver transplant for HCV cirrhosis will require treatment for recurrent HCV infection after receiving a liver transplant.[11]

Regardless of HIV status, failure to test people who meet HIV screening criteria for chronic viral hepatitis infection is a missed opportunity to prevent future need for liver transplant and HCC; or at least diagnose HCC at a curable stage.

Andrew de la Torre, MD, is a liver transplant surgeon at University Hospital-UMDNJ in Newark, NJ, Assistant Professor of Surgery, UMDNJ-New Jersey Medical School and appointee to the New Jersey State Viral Hepatitis Advisory Committee.

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CME

Hepatitis B and HIV Co-infection - Continuing Education Information

Release Date: August 1, 2006
Expiration Date: June 30, 2008
Course Code: 08HC02-DE01

Target Audience:

This activity is designed for physicians and nurses, and for other health care professionals in New Jersey.

Statement of Need

Co-infection with the human immunodeficiency virus (HIV) and the hepatitis B virus (HBV) presents a significant challenge to health care providers, affecting approximately 10% of persons with HIV infection. It is important to screen all HIV infected individuals for HBV infection. HIV/HBV co-infected individuals are at increased risk of chronic hepatitis, cirrhosis, and hepatocellular carcinoma, and of experiencing HAART toxicity. Provider knowledge of HBV status will affect routine laboratory monitoring and the selection of appropriate treatment regimens for HIV as well as HBV. Further research is needed on the most effective approach to co-management, however, there is evidence that antiretroviral treatment for HIV can slow the progression of liver damage due to HBV. Health care providers should also be aware of the importance of risk reduction including reduction or cessation of alcohol and acetaminophen use.

The most recent HIV treatment recommendations are the May 4, 2006 "Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents." This report explains the new recommendations for treating patients who are co-infected with HBV and HIV, including staging HBV and HIV treatment, based on the stage of each disease. It also outlines the optimal treatment options, whether the patient is treated for HBV first, HIV first, or HIV and HBV together.

Learning Objectives

Upon the completion of this activity, participants should be able:

- To recognize the role of laboratory testing for the diagnosis and ongoing monitoring of HBV/HIV infected patients.
- To describe preventive measures for close contacts of HIV-HBV co-infected persons.
- To identify HBV treatment candidates and implement evidence-based treatment regimens for the management of HBV in HIV co-infected patients.

Method of Instruction

Participants should read the learning objectives and review the activity in its entirety. After reviewing the material, complete the self-assessment test consisting of a series of multiple-choice and True/False questions.

Upon completing this activity as designed and achieving a passing score of 70% or more on the self-assessment test, participants will receive a credit letter and the test answer key four (4) weeks after receipt of the self-assessment test, registration, and evaluation materials.

Estimated time to complete this activity as designed is 1 hour.

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This activity was reviewed for relevance, accuracy of content, balance of presentation, and time required for participation by Bonnie Abedini, BSN, MS; Mary C. Krug RN, MSN, APN-C; Debbie Y. Mohammed, MS, APRN-BC, ACRN; and Patricia M. Kloser, MD, MPH

The activity was prepared in accordance with the ACCME Essentials. This activity was reviewed for relevance, accuracy of content, balance of presentation, and time required for participation by Patricia Kloser, MD, MPH.

Faculty

Mark Gentz, DO, is an Infectious Disease specialist in Richmond Virginia. He completed his fellowship and residency at Kennedy Memorial Health System, through the School of Osteopathic Medicine in Stratford, NJ.

Sindy M. Paul, MD, MPH, is Medical Director for the New Jersey Department of Health and Senior Services (NJDHSS), Division of HIV/AIDS Services; Assistant Clinical Professor at the University of Medicine and Dentistry of New Jersey (UMDNJ); and President, New Jersey Board of Medical Examiners

Eugene Martin, PhD, is Associate Professor of Pathology and Laboratory Medicine at UMDNJ at Robert Wood Johnson Medical School and Administrative Director, University Diagnostic Laboratories (UDL).

Disclosure

In accordance with the disclosure policies of UMDNJ and to conform with ACCME and FDA guidelines, all program faculty are required to disclose to the activity participants: 1) the existence of any financial interest or other relationships with the manufacturers of any commercial products/devices, or providers of commercial services, that relate to the content of their presentation/material, or the commercial contributors of this activity, that could be perceived as a real or apparent conflict of interest; and 2) the identification of a commercial product/device that is unlabeled for use or an investigational use of a product/ device not yet approved.

Faculty Disclosure Declarations

Patricia Kloser, MD, MPH (Field Tester and Activity Director) has the following financial relationships to disclose: Speaker's Bureau: GlaxoSmithKline, Roche; Consultant: Gilead, Boehringer Ingleheim.

The following have no financial relationships to disclose: faculty: Mark Gentz, DO; Eugene Martin, PhD; Sindy M. Paul, MD, MPH; and field testers: Bonnie Abedini, BSN, MS; Mary C. Krug RN, MSN, APN-C, and Debbie Y. Mohammed, MS, APRN-BC, ACRN.

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Disclaimer

The views expressed in this activity are those of the faculty. It should not be inferred or assumed that they are expressing the views of NJDHSS-Division of HIV/AIDS Services, UMDNJ, or any manufacturer of pharmaceuticals.

The drug selection and dosage information presented in this activity are believed to be accurate. However, participants are urged to consult the full prescribing information on any agent(s) presented in this activity for recommended dosage, indications, contraindications, warnings, precautions, and adverse effects before prescribing any medication. This is particularly important when a drug is new or infrequently prescribed.

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Center for Continuing & Outreach Education
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David Rosen, MSW, LCSW, Interim Director
Patricia C. Kloser, MD, MPH, Medical Director

30 Bergen Street, ADMC 710
PO Box 1709
Newark, New Jersey 07101-1709
973-972-3690: phone
973-972-3371: fax
http://umdnj.edu/ccoe/aids

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Editor
Kimi Nakata, MSW, MPH
ccnakata@umdnj.edu

Contributing Writers
Brenda Christian, MEd, PA-C;
David Condoluci, DO; Mark Gentz, DO, Eugene Martin, PhD, and Sindy M. Paul, MD, MPH

Medical Advisor
Sindy M. Paul, MD, MPH,
New Jersey Department of Health and Senior Services

Hepatitis B (HBV) and HIV

CME

Mark Gentz, DO, Sindy M. Paul, MD, MPH, Eugene Martin, PhD

Learning Objectives

Upon completion of this activity, participants should be able:

- **To recognize the role of laboratory testing for the diagnosis and ongoing monitoring of HIV/HBV infected patients.**
- **To describe preventive measures for close contacts of HIV-HBV co-infected persons.**
- **To identify HBV treatment candidates and implement evidence-based treatment regimens for the management of HBV in HIV co-infected patients.**

Introduction

Together human immunodeficiency virus (HIV) and hepatitis B virus (HBV) affect over one third of the world's population.[1] The HIV/HBV co-infection is common due to shared routes of transmission between the viruses. It is estimated that up to 10% of HIV infected individuals are co-infected with chronic HBV.[2] Numerous studies have shown that HIV affects the natural course of HBV infection, leading to an increased incidence of chronic hepatitis, cirrhosis, and hepatocellular carcinoma.[3,4] Chronic hepatitis has also been associated with severe hepatotoxicity in association with highly active antiretroviral therapy (HAART).[5] This article will provide an overview of HIV/HBV co-infection and treatment.

Together human immunodeficiency virus (HIV) and hepatitis B virus (HBV) affect over one third of the world's population

Virology

HBV is a partially double stranded, relaxed, circular, enveloped DNA virus of the family Hepadnaviridae.[4] There are eight HBV genotypes, (A-H), each of which exhibits a distinct geographical distribution. In the United States, genotypes A and C are the most common. Disease severity and response to antiviral treatment appear to be related to HBV genotype,[6] but at the present time there is insufficient data to recommend routine genotyping of the co-infected patient.

Epidemiology

The World Health Organization estimates that approximately 2 billion people have been exposed to HBV worldwide.[1] More than 350 million of these individuals are chronically infected, with over one million residing in the United States.[7] Although the majority of chronically infected individuals will remain asymptomatic carriers, many others will develop significant hepatic disease.[2]

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There are more than 40 million cases of HIV worldwide, with an estimated 1-1.2 million infected persons in the United States.[8] In New Jersey, surveillance data indicates that over 33,000 individuals were living with HIV/AIDS as of mid 2005.[9]

Transmission

HIV and HBV can be transmitted perinatally, sexually, and through contact with infected blood and body fluids.[1,8] In the United States, the most common routes of HBV transmission are through injection drug use (IDU) and sexual contact.[9] Prior to widespread HBV immunization of health care workers, HBV was a major occupational hazard. Although HIV and HBV share common transmission routes, HBV is 50-100 times more infectious than HIV.[1] The most common route of HIV transmission remains sexual contact. Between 2001-2004, men who have sex with men (MSM) represented the largest proportion of U.S. HIV diagnoses (44%), followed by adults and adolescents infected through heterosexual contact (34%).[10]

Although HIV and HBV share common transmission routes, HBV is 50-100 times more infectious than HIV

Clinical Manifestations of HBV Infection

Acute HBV infection can range in presentation from asymptomatic disease to fulminant hepatic failure. Approximately 70% of acute cases are asymptomatic although serum transaminases are commonly elevated. Symptomatic HBV can range in presentation from mild to severe disease. The usual symptoms include low-grade fever, arthralgias, right upper quadrant pain, headache, nausea, and loss of appetite.[2] Physical exam findings include right upper quadrant tenderness and hepatomegaly. Scleral icterus can occur once the serum bilirubin level exceeds 2.5 mg/dl. The patients may complain of dark urine and light or clay colored stools.

Chronic HBV may be asymptomatic, or may cause nonspecific symptoms, such as, fatigue and intermittent right upper quadrant pain. Once the disease progresses to cirrhosis and hepatic decompensation, stigmata of end stage liver disease (ESLD) begins to appear. Patients may develop ascites, caput medusa, jaundice, variceal bleeds, and hepatic encephalopathy.[2] Uncommon extrahepatic complications of chronic HBV include glomerular disease, polyarteritis nodosa, and vasculitis.[2]

Natural History of HBV Infection

Acute HBV infection results in either acute or chronic disease. The majority of immunocompetent adults will generate an immune response (HBsAb), and ultimately clear the virus.[10] However, approximately 5-10% of adult patients will develop chronic HBV.[10] The majority of these chronically infected individuals will remain inactive carriers, but a small number will experience progressive liver disease.[10] Several risk factors have been associated with progressive liver disease. These include: older age, an elevated HBV viral load, persistence of HBeAg, and elevated aminotransferase levels.[10] Based on individual risk factors, the risk of developing cirrhosis can vary between 0.1 and 10% per year.[4] Individuals who develop cirrhosis are subsequently at higher risk for developing decompensated liver failure, and hepatocellular carcinoma.[10]

Impact of HIV on HBV Progression

Numerous studies have documented a deleterious effect of HIV on HBV liver disease. In the Multicenter Cohort Study (MACS), the authors found that HIV/HBV co-infected individuals, especially those with low CD4 counts, were at a higher risk for liver-related mortality than HBV mono-infected individuals.[3] Several cross-sectional studies have demonstrated other negative sequelae of co-infection. These studies found a higher incidence of HBeAg positivity and possible elevation of serum HBV DNA levels in HIV/HBV co-infected patients, which may be related to NRTI use.[12,13] Another study found HIV/HBV co-infected individuals to demonstrate a higher incidence of biopsy-proven cirrhosis and a higher level of HBV replication than HBV mono-infected individuals.[14]

Impact of HBV on HIV Progression

If left untreated, HIV results in serious complications and death. Hepatitis B is usually more slowly progressive and can take years or even decades to cause serious liver damage. Chronic liver diseases, such as cirrhosis and liver cancer, occur in 15 to 25 percent of people infected with hepatitis B alone.

A study of survival outcomes among HIV-HBV co-infected patients at the HIV Atlanta Veterans Affairs Cohort Study (HAVACS) indicates the importance of treating HIV infection regardless of its potential association with liver injury. Survival, both from HIV infection and from AIDS to death, did not significantly differ in HBV co-infected patients compared to the remaining patients. However, the use of HAART, and particularly of 3TC (Epivir®, lamivudine) and TDF (tenofovir disoproxil fumarate, Viread®), exerted a protective effect at any stage of HIV disease, with significant decreases in the risk of death.[15] Other studies also

suggest that HBV cannot be implicated in adversely affecting the course of HIV disease.[4]

Nevertheless, people co-infected with HIV and hepatitis B may experience a more rapid progression of liver disease due to their weakened immune systems, but also because many of the medications used to treat HIV are metabolized in the liver and may augment pre-existing injury to the liver.

Many drug classes used in the treatment of HIV infection have been linked with liver toxicity[16] including: *Nucleoside Reverse Transcriptase Inhibitors* (NRTIs) such as AZT (Retrovir®); ddI (Videx®), d4T (Zerit®), ddC (Hivid®), and abacavir (Ziagen®); *Non-Nucleoside Reverse Transcriptase Inhibitors* (NNRTIs) such as Nevirapine (Viramune®); *Protease Inhibitors* (PIs), such as Ritonavir (Norvir®) appear to produce the majority of liver related toxicity although Indinavir (Crixivan®) has also been associated with liver toxicity. Saquinavir (Fortovase®) is much less toxic but the combination of saquinavir and ritonavir increases the potential for liver damage significantly. Kaletra® combines lopinavir with ritonavir, and is known to elevate liver enzymes.

Because PI's are given with small doses of ritonavir, liver function needs to be monitored frequently. The potential for HIV medications to produce liver damage is very real. HIV medications may increase liver enzyme levels, but these will usually stabilize over time.

Recommendations appear below for drugs that are thought to be less prone to exacerbating pre-existing liver injury.

Diagnosis of HBV

All HIV-1 positive individuals should be tested for HBV co-infection. The current recommendations are for initial testing for hepatitis B surface antigen (HBsAg), hepatitis B core antibody (anti-HBc), and hepatitis B surface antibody (anti-HBs).[2] Together, these tests indicate whether a patient is infected, immunized, or has recovered from a previous infection.[10] Follow-up testing to determine the state of infectivity or partial seroconversion needs to be completed.

Three phases of chronic hepatitis B have been described, an initial so-called "immunotolerant phase," which is characterized by high levels of virus in the serum and little hepatic inflammation; a second or "active phase," which is associated with an intermittent or continuous hepatitis of varying degrees of severity; and an "inactive phase" during which viral concentrations are low, and there is minimal hepatic inflammatory activity.[17]

Hepatitis B surface antigen (HBsAg) is the primary indicator of HBV infection, usually appearing 1-10 weeks after the initial exposure.[18] In individuals who recover from acute infection, HBsAg becomes undetectable.

Anti-HBc is a lifelong marker of exposure to the hepatitis B virus. Following acute infection, IgM anti-HBc is detectable in the serum, usually converting to the IgG class within six months of infection. In patients with chronic hepatitis B infection, IgM anti-HBc may reappear during disease exacerbation. IgG anti-HBc will persist in the serum in both patients who clear the disease, and those who develop chronic HBV. Anti-HBc is not affected by immunization.

Hepatitis Be antigen (HBeAg) is a marker of active HBV replication and infectivity. Following acute HBV infection, the percentage of infected patients who become carriers varies with age. The risk is greatest in the very young and in the very old. The absence of HBeAg in a person who is HBsAg-positive does not mean that the individual is NOT infectious. The HBe seroconversion is ordinarily the first step in resolving a hepatitis B infection, and is generally associated with resolving liver function tests.

Usually HBe seroconversion begins with the development of a so-called "pre-core mutant."[19] This mutation arises during the natural course of the infection, and results in the inability of the virus to produce HBeAg. Patients who are anti-HBe-positive with elevated ALT concentrations and detectable HBV DNA, almost all carry the pre-core mutant although, anti-HBe-positive patients with normal ALT levels and undetectable HBV DNA also frequently carry the mutant.

By definition, chronic HBV infection is established when HBsAg is detectable for longer than 6 months with or without continuing liver enzyme abnormalities. The course of chronic hepatitis B can be quite variable, characterized in some patients by exacerbation and remission of inflammatory episodes, in others by continuous active hepatitis of varying degrees of severity, and in still others by only modest liver involvement. About 1% of anti-HB positive patients will clear HBsAg each year.[20]

Anti-HBs becomes detectable following clearance of HBsAg. Anti-HBs indicates immunity from either a previous exposure to HBV or immunization. Anti-HBs usually remains detectable for life. In some patients, appearance of Anti-HBs may take weeks to months to develop after disappearance of HBsAg. During this period IgM anti-HBc may be the only serological marker of infection.

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Tables 1 and 2 provide a glossary of HBV markers as well as an interpretation algorithm.

Laboratory Monitoring

Most authorities recommend regular laboratory monitoring to assess liver disease in individuals infected with chronic HBV. Testing should be performed at a minimum of six-month intervals.[2] In patients with unstable disease, testing should be performed on a more frequent basis. Recommended tests include, a complete blood count with platelets, ALT, albumin, bilirubin, and prothrombin time.[2]

Hepatitis B viral DNA (HBV DNA) is a marker of active viral replication. It can be measured both quantitatively and qualitatively. There are several commercial assays available but they are not standardized. HBV DNA levels can fluctuate during HBV disease.[7] It is therefore important to obtain serial HBV DNA levels to monitor disease activity.

Table 1:
Interpretation of the Hepatitis B Panel

Tests	Results	Interpretation
HBsAg anti-HBc anti-HBs	negative negative negative	Susceptible
HBsAg anti-HBc anti-HBs	negative positive positive	Immune due to natural infection
HBsAg anti-HBc anti-HBs	negative negative positive	Immune due to hepatitis B vaccination
HBsAg anti-HBc IgM anti-HBc anti-HBs	positive positive positive negative	Acutely infected
HBsAg anti-HBc IgM anti-HBc anti-HBs	positive positive negative negative	Chronically infected
HBsAg anti-HBc anti-HBs	negative positive negative	Four interpretations possible *

CDC. Hepatitis B Frequently asked questions. Available at: http://www.cdc.gov/ncidod/diseases/hepatitis/b/faqb.htm

* Four Interpretations:

1. Might be recovering from acute HBV infection.
2. Might be distantly immune and test not sensitive enough to detect very low level of anti-HBs in serum.
3. Might be susceptible with a false positive anti-HBc.
4. Might be undetectable level of HBsAg present in the serum and the person is actually chronically infected.

Preventive Care in HIV/HBV Co-Infected Individuals

All patients with chronic HBV should be advised to avoid or stop the use of alcohol. End stage liver disease is known to occur at a younger age in heavy drinkers.[21] Patients should also be warned against the habitual use of high doses of acetaminophen (› 2-4 g/day).[2]

HBV can be transmitted to susceptible household contacts, sexual partners, and through needle sharing. In the United States, all children and health care workers now routinely receive hepatitis B vaccine. Many adults, however, never received the vaccine and remain susceptible to the virus. HBV has been transmitted through sharing of toothbrushes and razors. Infected individuals should be counseled about household transmission of HBV. Contacts at risk should be encouraged to obtain HBV immunization.

Patients diagnosed with chronic HBV should be screened for hepatitis A virus (HAV) and hepatitis C virus (HCV). Persons not immune to HAV should receive HAV immunization.[21] There is no vaccine for HCV. Individuals found to be HCV positive will need further studies to determine viral load and genotype if the disease is active. HCV negative individuals should be counseled on risk factors for acquisition of HCV. Patients should also be warned of the potential serious sequelae of HBV/HCV co-infection.

Chronic HBV infection places individuals at risk for hepatocellular carcinoma (HCC). Concomitant risk factors include, hepatitis C virus (HCV) co-infection, advanced age, cirrhosis, male gender, and family history of HCC.[7] The incidence of HCC in HIV/HBV co-infected individuals has not been studied.[2] Authorities recommend periodic (every 6-12 months) alfa-fetoprotein (AFP) and ultrasound screening among patients with persistent HBsAg, especially those in a group at high risk.[2]

Who Should Be Treated

Consensus Panel Guidelines vary slightly in their recommendations for treatment candidacy in HIV/HBV co-infected individuals.[2,6] The recommendations from the CDC, Infectious Diseases Society of America, and National Institutes of Health advocate treatment for patients who are HBeAg positive or demonstrate serum HBV DNA levels greater than 100,000 copies/mL.[2] In addition, serum ALT levels must be elevated or moderate disease activity

or fibrosis must be present on liver biopsy.[3] The International Panel for Care of Patients with Chronic Hepatitis B and HIV Co-Infection recommends that anti-HBV treatment be considered in all patients with any sign of liver disease. This includes elevated aminotransferases, elevated HBV DNA levels, or evidence of liver pathology on biopsy.[6]

Aminotransferases and serum HBV DNA fluctuate in co-infected individuals.[7] Disease flares can be associated with significant morbidity. It is therefore important to obtain serial measurements of these markers to accurately determine disease activity. The decision to treat HBV should be made independently of HIV related immunosuppression.

Treatment Goals

Some specialists consider the goal of HBV treatment to be HBsAg seroconversion.[2] The primary goal, however, is minimization of disease progression rather than viral eradication.[4] Markers of effective treatment include decreasing HBV DNA levels, normalization of aminotransferases, improvement of liver histology, and development of anti-HBe. Effective HBV treatment is associated with less HAART related toxicity, a lower risk of HCC, and a decreased risk of HBV transmission to others.

Table 2: Glossary of Hepatitis B Markers

HBsAg	A serologic marker on the surface of HBV. It can be detected in high levels in serum during acute or chronic hepatitis. The presence of HBsAg indicates that the person is infectious. The body normally produces antibodies to HBsAg as part of the normal immune response to infection.
anti-HBs	The presence of anti-HBs is generally interpreted as indicating recovery and immunity from HBV infection. Anti-HBs also develops in a person who has been successfully vaccinated against hepatitis B.
anti-HBc	Appears at the onset of symptoms in acute hepatitis B and persists for life. The presence of anti-HBc indicates previous or ongoing infection with hepatitis B virus (HBV) in an undefined time frame.
HBeAg	A secreted product of the nucleocapsid gene of HBV and is found in serum during acute and chronic hepatitis B. Its presence indicates that the virus is replicating and the infected individual has high levels of HBV.
anti-HBe	Produced by the immune system temporarily during acute HBV infection,or consistently during or after a burst in viral replication. Spontaneous conversion from e antigen to e antibody (a change known as seroconversion) is a predictor of long-term clearance of HBV in patients undergoing antiviral therapy and indicates lower levels of HBV.
IgM anti-HBc	Positivity indicates recent infection with HBV (6 mos). Its presence indicates acute infection.

Adapted from: CDC. Hepatitis B Frequently asked questions. Available at: http://www.cdc.gov/ncidod/diseases/hepatitis/b/faqb.htm

Antiretroviral Agent Considerations for Patients with HIV-HBV Co-Infection

It is unclear if HBV treatment improves the course of HIV, nor is there evidence that HIV treatment alters the course of HBV. However, several hepatic complications that may be due to flares in HBV activity or toxicity from antiretroviral agents can affect HIV treatment in co-infected patients.[22]

- Emtricitabine, lamivudine, and tenofovir have activity against both HIV and HBV. Discontinuation of these medications can potentially result in serious hepatocellular damage due to a flare of HBV. If any of these medications is discontinued, frequent liver function and HBV tests should be used to monitor the patient. Adefovir dipivoxil or entecavir should be considered to prevent flares, especially in patients with marginal hepatic reserve.[22]
- Treatment of chronic HBV with lamivudine monotherapy can result in resistance when lamivudine is the only active drug for HBV in co-infected patients. The level of resistance is 40% at two years and approximately 90% at four years. [22]
- Deterioration of liver function tests has been associated with immune reconstitution. This may occur because HBV is primarily an immune-mediated disease.[22]
- Patients with immune reconstitution may lose HbeAg that is associated with a hepatitis flare. [22]
- All protease inhibitors and NNRTIs are associated with a high rate of increased transaminase levels. The rate and magnitude of this increase is higher in co-infected patients.[22]

Antiviral Agents In HIV-HBV Co-Infected Individuals

Lamivudine and Emtricitabine

Lamivudine (3TC) is a nucleoside analogue with activity against both HIV and HBV.[23] Lamivudine is well tolerated and is a common component of HAART regimens. A major concern often seen when using this medication is the rapid development of HBV resistance. Resistance to lamivudine in HIV/HBV co-infected individuals is estimated to occur at a rate of 20% per year.[4]

Emtricitabine (FTC) is a nucleoside analogue very similar to lamivudine. Emtricitabine has activity against both HIV and HBV.

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Emtricitabine should not be used against lamivudine resistant viruses.[2] Like lamivudine, emtricitabine is well tolerated and it is a common component of many HAART regimens.

Lamivudine and emtricitabine should be considered equivalent to one another due to their structural similarity. These drugs should not be used simultaneously. Both drugs possess low genetic barriers to resistance.[6]

Interferon

Interferon alfa 2a and 2b along with pegylated interferon alfa 2a are approved for treatment of chronic HBV in HIV seronegative patients. Pegylated interferon has also been approved for use in HIV/HCV co-infected individuals. Interferon is not active against HIV. Studies have shown pegylated interferon to be more efficacious than standard interferon in HBeAg positive individuals.[6] Interferon treatment is associated with many side effects that limit its use. Interferon can precipitate a drop in CD4 cells and must be used with caution in patients with borderline immune function.[6] In addition, interferon therapy is contraindicated in patients with decompensated liver disease. Data regarding pegylated interferon in HIV/HBV infected individuals is limited.[6]

Adefovir Dipivoxil

Adefovir dipivoxil is a nucleotide analogue closely related to tenofovir.[6] Adefovir was originally developed as an antiretroviral drug, but further studies were halted, secondary to renal toxicity occurring at doses clinically affective against HIV.[10] At currently recommended doses, adefovir is well tolerated and displays potent HBV activity. It is not effective against HIV at low doses. Adefovir can be used against lamivudine resistant viruses.[2]

Tenofovir Disoproxil Fumarate

Tenofovir is a nucleotide analogue with activity against both HIV and HBV. It is well tolerated and has activity against lamivudine resistant virus.[2] Emtricitabine is available, co-formulated with tenofovir in a single capsule, marketed under the name Truvada®. Studies have shown that tenofovir, in combination with lamivudine, is associated with a greater decrease in HBV DNA viral load than in patients treated with lamivudine alone.[10]

Entecavir

Entecavir is a nucleotide analogue recently approved for chronic HBV use in 2005. It is well tolerated and has no activity against HIV. Although entecavir can be used against lamivudine resistant virus, there has been documented resistance against entecavir in this population.[10]

TREATMENT

Management of chronic HBV in the HIV infected patient is complicated and requires individualized treatment. Treatment regimens will vary based on the patient's immune function as well as HBV status. Consensus panel guidelines for HIV/HBV co-infected individuals are available from several authorities.[2,6,11] Each report differs slightly in its recommendations for patient management.

The primary goal, however, is minimization of disease progression rather than viral eradication

The primary goal in the care of HIV/HBV co-infected individuals is HIV suppression.[2] If there are no contraindications, HAART selections should include, antiretrovirals with activity against both HIV and HBV. Agents with dual activity against HIV and HBV include lamivudine, emtricitabine, and tenofovir.

Approximately 15% of patients will experience hepatitis flares when HBV treatment is discontinued.[2] It is important to monitor patients very closely when therapy is changed or stopped.

The Department of Health and Human Services (DHHS) Panel on Antiretroviral Guidelines for Adults and Adolescents convened and published revised recommendations for co-management of HIV and HBV in the May 4, 2006 Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents.[22] These recommendations are summarized below.

- **Treatment of HIV and not HBV**
  The combination of tenofovir + emtricitabine or tenofovir + lamivudine can be used as the nucleoside reverse transcriptase inhibitor (NRTI) backbone of an antiretroviral regimen. To avoid the development of resistance, emtricitabine, tenofovir, or lamivudine should not be the only medications with anti-HBV activity in the regimen.[22]
- **Treatment of HIV and HBV**
  The combination of tenofovir + emtricitabine or tenofovir + lamivudine should be considered the first-choice NRTI option. Emtricitabine and tenofovir can be given as a single once daily pill (Truvada®) to simplify often complicated treatment regimens. Alternatives include entecavir alone or in combination with one of the three nucleosides with activity against both HIV and HBV.

To avoid the development of resistance, emtricitabine, tenofovir, or lamivudine should not be the only medications with anti-HBV activity in the regimen.[22]

- **Treatment of HBV and not HIV**
  Patients not requiring HIV treatment should utilize antivirals that have no activity against HIV. This strategy will reduce selection of HIV resistance and preserve future HIV treatment options. Pegylated interferon-alpha is an option that will not lead to HIV or HBV drug resistance.[22] Interferon generally demonstrates a higher rate of HBeAg seroconversion than nucleoside or nucleotide analogues.[6] Interferon can precipitate a drop in CD_4 cells, and must be used with caution in patients with borderline immune function. In addition, interferon therapy has many side effects and is contraindicated in patients with decompensated liver disease.

  Because entecavir is a nucleoside analogue that is not active against HIV, it is another option. Adefovir dipivoxil is not active against HIV at the 10mg dose; however, HIV resistance could theoretically develop because it is related to tenofovir. The use of emtricitabine, tenofovir, or lamivudine without a full regimen of HAART should be avoided because drug resistant HIV mutations could rapidly develop.[22]

Conclusion

HIV/HBV co-infection presents a significant challenge to health care providers. It is important that all HIV infected individuals are screened for HBV infection. Co-infected individuals are at increased risk of chronic hepatitis, cirrhosis, and hepatocellular carcinoma as well as HAART toxicity. Knowledge of HBV status will affect routine laboratory monitoring as well as treatment regimen. Future research is needed to study treatment regimens in the HIV/HBV co-infected population.

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CME

Gaps in Care:
a Case Presentation on HIV and HBV Co-Infection

David V. Condoluci, DO,FACOI

Case presentation

C.L. is a 23 year-old HIV positive male who was diagnosed in April 2003. The initial CD4 count was 761 with a viral load of 1,180. C.L. had been lost to follow-up but re-engaged in treatment in October 2005. His viral load and CD4 count remained stable and he did not require medications. He presented to the clinic in February 2006 complaining of fever and a rash.

On physical exam he appeared alert and oriented x three.

Temp	97.6ºF
BP	124/74
Heart rate	80 bpm
Respirations	20
HEENT	unremarkable
Heart	RRR with no murmurs
Lungs	clear to auscultation
Abdomen	soft, normal bowel sounds, no masses, and no hepatosplenomegaly
Extremities	no edema, clubbing or cyanosis
Skin	diffuse macular papular rash over his entire body including palms and soles of his feet

Laboratory data was as follows:

Test	Finding	Normal range/ result
WBC	6.2 x 10-3	(4.5 – 11.0:)
SGPT	127 U/L	(0 – 35)
SGOT	75 U/L	(0 – 40)
Bilirubin	Total 0.7 mg/ml;	(0 – 1.0)
RPR	reactive at 1:64	(Nonreactive)
FTA	positive	Negative

Diagnosis: Secondary syphilis

Rx: 2.4 M U IM Benzathine, Penicillin G weekly x three

A repeat exam one month later showed resolution of the rash and essentially a normal exam, although the patient reported continuing fatigue. A new laboratory evaluation, with hepatitis screening due to elevated levels at the previous tests, showed:

Test	Finding	Normal range/ result
WBC	5.2 x 10-3	(4.5 – 11.0:)
SGPT	162 U/L	(0 – 35)
SGOT	117 U/L	(0 – 40)
Bilirubin	Total 0.7 mg/ml;	(0 – 1.0)
RPR	reactive at 1:8	(Nonreactive)
Hep B viral DNA	› 6 million	
Hep BE antigen	reactive	
Hep BE antibody	non-reactive	
Hep B Surface antigen	reactive	
Hep B Surface antibody	negative	

He was diagnosed as having acute hepatitis B infection and was treated with adefovir 10 mg per day. He has continued to show improvement in symptoms and in objective laboratory data.

Discussion

The above case illustrates some of the gaps that can exist in HIV care and treatment in spite of a comprehensive program. Behavioral Risk Assessments with focused behavioral interventions should be performed with every patient in treatment on an ongoing basis. Although time consuming, clinicians must seize every opportunity to counsel patients about the risks of unsafe sexual practices. In busy clinic settings, on-site counselors and educators need to be utilized to reinforce this information and to provide support and guidance when needed. Had C.L. been counseled he might have made better choices about his sexual activity and avoided syphilis and Hepatitis B infection.

The second gap in treatment was the lack of hepatitis B vaccination. Screening for hepatitis A, B and C should be a part of the initial evaluation for every HIV-infected patient and should be repeated annually if necessary. When patients test negative for hepatitis B Ab, the hepatitis vaccine should be offered and administered.

C.L. was not infected at his initial work-up, but was lost to follow-up, making it more unlikely that he would receive the much needed vaccine and be able to prevent his acquiring Hepatitis B. For this patient, private insurance did not cover immunizations and staff would have needed to obtain approval or refer the patient to a free or reduced-cost program.

In comprehensive HIV care, HAART is important in enhancing the immune system, and reducing the viral burden. Additional services such as nursing coordination of treatment and treatment adherence, pain management, and nutritional support also contribute to the well-being of the HIV-positive patient. But

prevention plays an integral part in the treatment of HIV-infected individuals as well, empowering patients with knowledge of how to take better care of themselves, i.e. proper nutrition, dental checkups, Gyn evaluations and yearly PAP smears. Risk reduction counseling, including risk assessment with focused behavioral interventions, will reinforce prevention messages including safer sex practices to protect patients from acquiring or transmitting other sexually transmitted diseases and preventing the transmission of HIV and other STDs to partners. Following screening for hepatitis A, B, and C, patients who do not have antibody for hepatitis A or hepatitis B should be given a combination vaccine for both hepatitis A and B, TwinRx®, as it can immunize for both infections with one vaccine. This is given as a 3 part series of injections at day 1 (0), 1 month, and 6-12 months. Medical prevention also includes immunizations such as Varicella vaccine, flu vaccine and Pneumovax.

Caring for HIV-infected patients is both comprehensive and challenging. C.L. developed hepatitis B, a preventable infection, because he did not return appropriately for medical evaluation and care, and because he chose to engage in unprotected sex that resulted in secondary syphilis. But the final question is, as clinicians, what could we have done to prevent this from happening?

David V. Condoluci, DO,FACOI is Clinical Professor of Medicine at UMDNJ-School of Osteopathic Medicine and Medical Director of Garden State Infectious Disease Associates in Voorhees, NJ.

Note

Information on immunizations for HIV-positive children and adolescents will appear in the next issue of NJ AIDSLine.

CME

HEPATITIS B SCREENING: A Quality Assurance Perspective

A decision to treat the HIV-HBV co-infected patient is complex and requires individualized consideration. While we do not know whether treatment for HBV improves mortality in HIV, we do know that individuals infected with both HIV and hepatitis B may experience an accelerated progression of liver disease because of their compromised immune system. Couple this with the known hepatotoxicities of many medications used to treat HIV and the message becomes very clear that prevention is the key to quality survival.

Caring for the HIV-infected patient requires a multi-faceted approach. It is not enough to monitor the CD_4 and viral load and prescribe medications aimed at enhancing the immune system and reducing viremia. To ensure that the patient receives quality care, the treatment plan must also include focused behavioral interventions to support prevention.

Every patient infected with HIV must be screened for hepatitis B. Screening should take place as a part of the initial evaluation and should be repeated annually thereafter if necessary. If test results confirm that the patient has neither recovered from nor been immunized against the HBV, the hepatitis B vaccine should be administered. Careful follow-up to ensure patient compliance is essential. Prospectively scheduling vaccinations, periodic chart reviews, follow-up reminders, phone calls, and letters may be necessary, and clinicians need to make hepatitis and other screenings as high a priority as assessing CD_4 counts when evaluating patients.

Paramount to any screening initiative is targeted prevention messages. Health care providers must ensure that patients clearly understand the mode of transmission for diseases and are educated about the behaviors necessary for prevention. Safer sex practices will not only decrease the likelihood of spreading HIV but will also decrease the possibility that the patient will acquire hepatitis B or other sexually transmitted diseases.

Brenda J. Christian, MEd, PA-C; Quality Specialist; UMDNJ-CCOE-Division of AIDS Education

CME

University of Medicine and Dentistry of New Jersey - Center for Continuing and Outreach Education

Hepatitis B and HIV Co-infection
Self Assessment Test

Questions refer to the content of the article and the case review that follows. To receive continuing education credit [1 AMA/PRA category 1 credit™ or 1.2 continuing education contact hours for nurses]: complete post-test, registration, and evaluation forms on-line at http://ccoe.umdnj.edu/catalog/aids or fill in the forms on the next 2 pages, and mail or fax to UMDNJ-CCOE (see next page).

1) Which of the following is the estimated prevalence of chronic hepatitis B infection in HIV infected individuals?

a) 5%
b) 10%
c) 15%
d) 20%

2) In the U.S., the most common routes of HBV transmission are injection drug use and what else?

a) blood transfusion
b) needle stick injury
c) perinatal
d) sexual contact

3) What percentage of acute HBV infection cases are asymptomatic?

a) 50%
b) 60%
c) 70%
d) 80%

4) Which of the following is an extrahepatic complication of chronic HBV?

a) pericarditis
b) pleural effusion
c) polyarteritis nodosa
d) pyelonephritis

5) Which of the following HBV markers indicates recovery or immunity from HBV infection?

a) IgM anti-HBc
b) anti-HBc
c) anti-HBs
d) HBsAg

6) Which of the following HBV markers indicates recent infection with HBV?

a) IgM anti-HBc
b) anti-HBc
c) anti-HBs
d) HBsAg

7) A patient presents with the following HBV serology: HBsAg positive, anti-HBc positive, IgM anti-HBc negative, anti-HBs negative. What does this indicate?

a) acutely infected
b) chronically infected
c) immune due to natural infection
d) immune due to HBV vaccination

8) A patient presents with the following HBV serology: HBsAg negative, anti-HBc negative, anti-HBs positive. What does this indicate?

a) actively infected
b) chronically infected
c) immune due to natural infection
d) immune due to HBV vaccination

9) Which of the following is recommended to assess liver disease in individuals infected with chronic HBV?

a) alkaline phosphatase
b) creatinine
c) prothrombin time
d) sodium

10) Which of the following antivirals has NO activity against HIV?

a) emtricitabine
b) entecavir
c) lamivudine
d) tenofovir

CE Activity Code: 08HC02 - DE01**DE01**

University of Medicine and Dentistry of New Jersey - Center for Continuing and Outreach Education

Hepatitis B and HIV Co-infection

Registration Form

In order to obtain continuing education credit, participants are required to:

(1) Read the learning objectives, and review the activity, and complete the self-assessment.

(2) Complete this registration form and the activity evaluation form on the next page, and record your test answers below

(3) Send the registration and evaluation forms to:

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via mail: PO Box 1709, Newark, NJ 07101-1709

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(4) Retain a copy of your test answers. Your answer sheet will be graded and if you achieve a passing score of 70% or more, a credit letter awarding 1 AMA/PRA category 1 credit™ or 1.2 continuing education contact hours for nurses and the test answer key will be mailed to you within four (4) weeks.

Individuals who fail to attain a passing score will be notified and offered the opportunity to complete the activity again. This activity will be posted online at http://ccoe.umdnj.edu/aids

Please note: CE credit letters and long-term credit retention information will only be issued upon receipt of completed evaluation form.

SELF-ASSESSMENT TEST

Circle the best answer for each question on page 10.

1. A B C D	3. A B C D	5. A B C D	7. A B C D	9. A B C D
2. A B C D	4. A B C D	6. A B C D	8. A B C D	10. A B C D

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First Name_____ M.I.____ Last Name_____ Degree_____

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Fax #_____ E-mail_____

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Nurses: I attest that I have completed the activity as designed and am claiming [up to 1.2 hours] ____ continuing education contact hours for nurses from the NJSNA.

Physicians: I attest that I have completed the activity as designed and am claiming [up to 1 credit] ____ AMA/PRA category 1 credit.™

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University of Medicine and Dentistry of New Jersey - Center for Continuing and Outreach Education

Hepatitis B and HIV Co-infection
Activity Evaluation Form

The planning and execution of useful and educationally sound continuing education activities are guided in large part by input from participants. To assist us in evaluating the effectiveness of this activity and to make recommendations for future educational offerings, please take a few moments to complete this evaluation form. Your response will help ensure that future programs are informative and meet the educational needs of all participants.

Please note: CE credit letters and long-term credit retention information will only be issued upon receipt of this completed evaluation form. Thank you for your cooperation!

PROGRAM OBJECTIVES: Having completed this activity, are you better able to:	Strongly Agree				Strongly Disagree
Objective 1: Recognize the role of laboratory testing for the diagnosis and ongoing monitoring of HBV/HIV infected patients.	5	4	3	2	1
Objective 2: Describe preventive measures for close contacts of HIV-HBV co-infected persons.	5	4	3	2	1
Objective 3: Identify HBV treatment candidates and implement evidence-based treatment regimens for the management of HBV in HIV co-infected patients.	5	4	3	2	1
OVERALL EVALUATION	Strongly Agree				Strongly Disagree
The information presented increased my awareness/understanding of the subject.	5	4	3	2	1
The information presented will influence how I practice.	5	4	3	2	1
The information presented will help me improve patient care.	5	4	3	2	1
The faculty demonstrated current knowledge of the subject.	5	4	3	2	1
The program was educationally sound and scientifically balanced.	5	4	3	2	1
The program avoided commercial bias or influence.	5	4	3	2	1
Overall, the program met my expectations.	5	4	3	2	1
I would recommend this program to my colleagues.	5	4	3	2	1

If you anticipate changing one or more aspects of your practice as a result of your participation in this activity, please provide us with a brief description of how you plan to do so.

_____

_____

_____

_____

Please provide any additional comments pertaining to this activity (positives and negatives) and suggestions for improvement. Please list any topics that you would like to be addressed in future educational activities:

_____

_____

_____

_____

CE Activity Code: o8HCo2 - DEo1

AIDS at 25

Highlights from the NJ HIV Clinical Update 2006

June 6, 2006

Kimi Nakata, Division of AIDS Education, UMDNJ – Center for Continuing and Outreach Education

Larry Ganges, Assistant Commissioner, Division of HIV/AIDS, New Jersey Department of Health and Senior Services (NJDHSS-DHAS), opened the conference by challenging the group of 216 clinicians and other healthcare professionals to look at the progress and remaining challenges at the 25-year anniversary of the discovery of the disease now known as AIDS. Many in the room had been involved in HIV/AIDS care and services for most of those years. Mr. Ganges and the other plenary speakers all noted the significant advances made in effective treatment, and yet how far we still are from either a cure or a slowing in new cases of infection.

... speakers all noted the significant advances made in effective treatment, and yet how far we still are from either a cure or a slowing in new cases of infection

The conference, co-sponsored by NJDHSS-DHAS with the UMDNJ-Center for Continuing and Outreach Education-Division of AIDS Education, offered a plenary session designed to update physicians, nurses, and other healthcare providers on recent advances in HIV/AIDS care and treatment, and examining the links between diagnosis, primary care, and HIV specialty care. Keynote speaker Dr. Roy "Trip" Gulick presented an update on "Treating the Experienced Patient," looking at markers and reasons for treatment failure, and available salvage regimens. Several speakers focused on the increasing role of HIV Rapid Testing. Sindy Paul, MD, MPH, Medical Director for the NJDHSS-Division of HIV/AIDS Services (DHAS) presented an overview and update on the use of rapid testing throughout New Jersey, including a demonstration of the test kits. Kathleen Casey, MD, Jersey Shore University Medical Center, described the links from diagnosis to care, changes with the advent of Rapid HIV Testing, and missed opportunities to identify HIV diagnoses. Patricia Kloser, MD, MPH, UMDNJ-Medical School and University Hospital, addressed the role of the HIV care provider as the primary care provider, and a holistic approach to incorporating HIV diagnosis and treatment into general primary care. David Condoluci, DO, presented on co-management of HIV with hepatitis B or C, and the increasing morbidity and mortality among people with HIV/AIDS that is associated with liver disease.

Conference registrants also participated in four breakout sessions designed to bridge theory and practice. A session on management of metabolic issues in HIV patients by Ronald Nahass, MD, of Infectious Disease Associates, included extensive discussion of lipodystrophies and cardiac implications of long-term HAART use. A multi-disciplinary team of staff from St. Michael's Medical Center, led by Stephen Mannochio, MD, and Dennis Smith, Prevention Case Manager, presented on their Prevention with Positives initiative. Dr. Kloser presented cases and held a skills-building workshop on case-based treatment. Jean Haspel, MSN, APN, from Infectious Disease Associates at Atlanticare Regional Hospital, presented and facilitated a workshop on medical management of HIV for non-clinicians.

IN THE NEWS!

TREATMENT UPDATE

The approval of two new HAART medications, protease inhibitor Prezista™ (darunavir) and once-daily regimen Atripla™, offers hope for HIV-infected persons with high levels of resistance, and simplicity for those encumbered by frequent, complicated dosing regimens.

TABLE 1. Drugs Contraindicated with Prezista™

CLASS	DRUG
Antihistamines	Astemizole (Hismanal®), Terfenadine (Seldane®)
Ergot Derivatives	Dihydoergotamine (Migranal®), Ergonovine Ergotamine (Cafergot®), Methylergonovine
GI Motility Agent	Cisapride (Propulsid®)
Neuroleptic	Pimozide (Orap®)
Sedative/ hypnotics	Midazolam (Versed®), Triazolam (Halcion®)

On June 23, 2006, Prezista™ (darunavir - formerly known as TMC-114), a protease inhibitor, was approved by the FDA for treatment experienced HIV-infected patients who have been previously unresponsive to other medications. Unlike its predecessor Aptivus™ (Tipranavir), Prezista™ may be stored at room temperature, does not require a high-fat meal for absorption, is not contraindicated in patients with Hepatitis B and C, and has fewer drug-drug interactions. More importantly, in clinical trials, patients who received the Prezista™-ritonavir combination had a greater log drop in viral load than the tipranavir trials and more patients were able to achieve virologic suppression below 50 than reported in the trials of its counterpart.

Prezista™ should be prescribed as a twice-daily regimen of 600 mg (two 300 mg tablets) with ritonavir 100mg and should be taken with food. Compared to other protease inhibitors, Prezista™ is tolerated well with few side effects. Diarrhea, nausea, vomiting, headache and skin rash are the side effects most commonly reported.

Prezista™ is CONTRAINDICATED in patients with known hypersensitivity to any of the product ingredients, and should be used with caution in patients with a known sulfonamide allergy, with diabetes, and hemophilia, and with certain medications.

As with the other protease inhibitors, darunavir is contraindicated or should not be co-administered with certain anticonvulsants, antihistamines, antimycobacterials, ergot derivatinves, GI motility agents, herbal products, HMC-CoA reductase inhibitors, neuroleptics, and sedative/hypnotics. (See Tables 1 and 2). A list of medications which may potentiate significant drug reactions is included in Table 3.

Darunavir is intended for use in combination with other HIV medications. Studies report no adverse effects when combined with the protease inhibitors amprenavir (Agenerase®), atazanavir (Reyataz™), indinavir (Crixivan®), lopinavir (Kaletra®), nelfinavir (Viracept®), ritonavir (Norvir®), saquinavir (Invirase®) or tipranavir (Aptivus™), the NRTIs abacavir (Ziagen®), didanosine (Videx®), emtricitabine (Emtiva™) , lamivudine (Epivir®), stavudine (Zerit®), tenofovir (Viread®), zalcitabine (Hivid®), or zidovudine (AZT), the NNRTIs delavirdine (Rescriptor®), efavirenz (Sustiva®), or nevirapine (Viramune®) and the fusion inhibitor enfuvirtide (Fuzeon™). The choice of active drug combinations varies from patient to patient and is dependent upon genotypic and phenotypic testing.

Darunavir is intended for use as salvage therapy in patients who are treatment experienced and unresponsive to previous therapy with protease inhibitors. Its use in pregnant females and treatment-naïve patients is currently being studied.

Darunavir offers hope for treatment-experienced patients who have exhausted all other options to achieve viral suppression. Studies have shown that combining darunavir with fusion inhibitor enfuvirtide (Fuzeon™) has the potential to reduce viral loads to undetectable levels. Even compromised nucleosides may offer an additional .5 to 1 log drop when added to a strong regimen including darunavir and one other active drug. Additionally, early data suggests that should a patient develop resistance to darunavir, tipranavir should remain active and vice versa.

TABLE 2. Drugs That Should Not Be Co-administered with Prezista™

CLASS	DRUG	CLINICAL COMMENT
Anticonvulsants	Carbamazepine (Tegretol®), Phenobarbital (Donnatal®), Phenytoin (Dilantin®)	Causes ↓darunavir plasma concentrations
Antimycobacterial	Rifampin (Rifadin®)	
Herbal Products	St. John's Wort (Hypercium perforatum)	
HMG-CoA Reductase Inhibitors	Lovastatin (Mevacor®), simvastatin (Zocor®)	Alteration in dose may be recommended due to potential risk of myopathy including rhabdomyolysis

IN THE NEWS!

Once-A-Day-Regimen

On July 12, 2006, the FDA approved the first ever once-daily single tablet regimen for HIV-infected patients. Atripla™ combines Truvada™, a two-NRTI combination comprised of 200 mg of emtricitabine (Emtriva™) and 300 mg of tenofovir (Viread®) with one NNRTI efavirenz (Sustiva®) 600mg. Sustiva® and Truvada™ are currently the most widely prescribed antiretroviral medications on the market, and DHHS guidelines endorse this triple drug combination therapy as a preferred regimen for treatment-naïve patients.

Atripla™ may be used alone or in combination with other active antiretroviral agents. Drug interactions have been noted when co-administered with didanosine, atazanavir, or lopinavir/ritonavir and dosage adjustments have been recommended. Atazanavir should be given with ritonavir when combined with Atripla™. Atripla™ should not be coadministered with lamivudine including Combivir®, Epivir®, Epzicom™ or Trizivir®.

Atripla™ is CONTRAINDICATED for use with astemizole (Hismanal®), cisapride (Propulsid®), midazolam (Versed®), triazolam (Halcion®), ergot derivatives or voriconazole. Use with St. John's work is not recommended. Atripla™ may decrease blood levels of methadone and may require an increase in methadone dosage. Efavirenz is a pregnancy class D drug, therefore pregnant women should not be prescribed Atripla™ unless there are no other therapeutic options, and women on Atripla™ should be advised to avoid pregnancy and breastfeeding.

The advent of Atripla™ means simplicity for the patient by providing a single-dose HAART regimen amenable to any life-style schedule. Simplicity means increased compliance, and ultimately reduced resistance.

It has been twenty-five years since the advent of the AIDS epidemic. For those of us who were treating patients then, AZT was the only treatment option. Our primary hope, as we watched our patients die, was that there would be new drugs to help combat the virus. But the arrival of new drugs brought heavy pill burdens, and complex regimens which patients were unable to tolerate. Missed doses lead to non-compliance and fewer treatment options in the face of increased drug resistance. Atripla™ makes HIV a truly manageable chronic disease. It will improve not only life span but quality of life as well. For those patients who have exhausted all the drug combinations we have to offer, darunavir sheds a ray of hope that they too can enjoy happier, healthier lives.

Brenda J. Christian, MEd, PA-C; Quality Specialist; UMDNJ-CCOE-Division of AIDS Education

Clinical Manual for Management of the HIV-Infected Adult (2006)

NEW UPDATE ON THE WEB

The Clinical Manual is now available as a free download on the AIDS Education & Training Centers (AETC) National Resource Center website: www.aidsetc.org

The guide was designed to serve as a practical everyday reference for a broad range of providers—physicians, pharmacists, nurse practitioners, advanced practice nurses, physicians assistants, dentists, and others who provide care to patients with HIV/AIDS. More than 90 chapters in ten sections were reviewed and updated.

The Clinical Manual includes sections focusing on the following topics:

(1) Testing and assessment
(2) Health maintenance and disease prevention
(3) Antiretroviral therapy
(4) Antiretroviral complications
(5) Complaint specific workups
(6) Disease specific treatment
(7) Pain and palliative care
(8) Neuropsychiatric disorders
(9) Special populations: Corrections
(10) Resources for clinicians and providers

CDC Hotline Changes

The former CDC HIV/STD hotline (800-342-2437) is now part of CDC-INFO (800-CDC-INFO), the new source for public health information from CDC. Calls to the former CDC HIV/STD hotline number are automatically being forwarded to CDC-INFO. This new service provides English, Spanish and TTY service, 24 hours a day, seven days a week.

As of January 2007, the old number (800-342-2437) will no longer be in service. CDC asks that you change hotline references:

New 24 Hour Hotline Number

CDC-INFO: 1-800-CDC-INFO
(800-232-4636)
1-888-232-6348 TTY
E-mail: cdcinfo@cdc.gov

If you have not already done so, please make this change as soon as possible on your website, printed materials, recorded messages on your own hotline (if you transfer calls to the CDC information service), and wherever else you may have the old number listed. For more information, see website: http://www.cdc.gov/hiv/hivinfo

References for "Missed Opportunites to Prevent Viral Hepatitis" on page 3.

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Reducing Perinatal HIV Transmission in New Jersey

March 23, 2007 - Princeton, NJ

Conference Purpose:

This program is designed to enhance the knowledge of physicians, nurses, physician assistants, case managers and others on the best practices for reducing perinatal (vertical) HIV transmission.

Conference Learning Objectives:

Upon completion of this program, participants will be able to:

- Discuss the epidemiology of perinatal (vertical) HIV transmission in NJ.
- Recognize the importance of counseling, rapid HIV testing, and short course therapy for women who present in labor with unknown HIV status.
- Identify risk factors and medical interventions to reduce the risk of perinatal (vertical) HIV transmission.
- Improve prenatal, intrapartum and postpartum management of the HIV positive woman and her HIV exposed infant through use of case studies.

Poster topics and Abstract Submissions:

Maternal transmission is the primary route of HIV infection in young children. Without intervention, 15-25% of formula fed infants born to HIV infected mothers will become infected. The vast majority of transmission occurs late in pregnancy or during labor and delivery. Today, risk of perinatal transmission can be as low as ‹2% with effective interventions.

This Call for Posters invites health care providers to submit abstracts detailing on-going research projects and/or innovative strategies in the area of reducing perinatal transmission of HIV. Abstracts should address at least one of the following key areas that impact perinatal transmission: Obstetrical Care, Counseling and Testing, HIV-exposed Infant Care, Epidemiology/Surveillance, Healthcare Policy and Access/ Retention in OB/GYN Care.

Call for Posters

Abstract Submission Guidelines

Abstracts that do not follow the guidelines listed below will not be reviewed. Please use one of the two following formats for abstract submission:

Format A: Research Based Interventions

1. Submitting author's contact information: first name, last name, degree, position, institution, institution mailing address, business phone, contact e-mail address;
2. Title of Poster Abstract: please use upper case letters;
3. Authors: all authors should be listed as follows: last name, first initial, institution, city/state;
4. Background: a concise statement of why the project or study was undertaken;
5. Objectives: clearly state the objectives of the study or program;
6. Methods: the investigational model used, including a description of the data collection method and the analysis conducted, control group used, and program developed to address the concerns of the objectives;
7. Results: specific findings, including an analysis of the data in tabular and statistical terms. What does the data show? What did the program accomplish? Present as much of the data as currently available.
8. Conclusions: summary of the findings that are supported by data results rather than opinion. If the study is still in progress and results are not available, state what has been accomplished.

Format B: Innovative Program Descriptions

1. Submitting author's contact information: first name, last name, degree, position, institution, institution mailing address, business phone, contact e-mail address;
2. Title of Poster Abstract: please use upper case letters;
3. Authors: all authors should be listed as follows: last name, first initial, institution, city/state;
4. Issues: a short summary of the issues addressed by the abstract;
5. Description: a brief description of the project, experience or intervention;
6. Lessons Learned: a brief description of project results;
7. Recommendations: further recommendations or next steps.

For EITHER format: when submitting a Poster Abstract, please follow these guidelines:

1. All abstracts must be submitted in English;
2. Deadline for submission is November 22, 2006;
3. The author(s) is/are responsible for all grammatical and factual details. No revisions will be accepted after the initial submission;
4. Abstracts should be submitted to: rosendv@umdnj.edu with the subject heading: 2007 Perinatal Conference Abstract;
5. The submitting author will be notified by e-mail of abstract receipt;
6. Notification of poster abstract disposition and poster specifications will occur by January 5, 2007;
7. All abstracts should use Times New Roman font, sized 12-point, single-spaced. The body is limited to 250 words (not counting section headers). The conference cannot guarantee optimal reproduction of tables, graphs or visual items within the body of the abstract.

Abstracts are considered official communication to the conference. For accepted abstracts, submitters agree to attend the conference and are expected to present their posters during scheduled poster sessions. All accepted submitters will be required to REGISTER for the conference independently of their abstract acceptance.

Accepted abstracts will be printed and distributed in conference hand-out packets to all participants and will be posted on-line. Submission of an abstract implies permission to publish in print and electronically, if accepted.

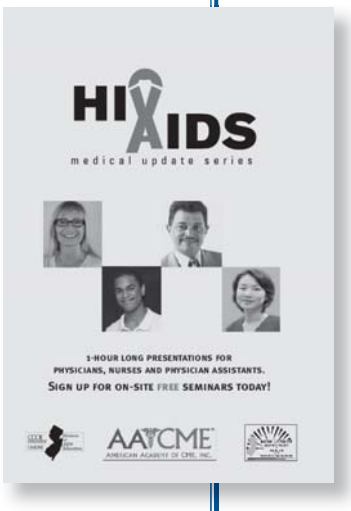
For questions about poster abstract submission, please contact David Rosen at rosendv@umdnj.edu or by phone at 973-972-7729.

Education and Training Resources for New Jersey Clinicians

Free On-site Training: HIV/AIDS Medical Update Series

Topics available:

- Diagnosis and Initial Management of HIV/AIDS: What the Primary Care Physician Should Know
- HIV/AIDS and Hepatitis C Co-Infection
- Immunizations for HIV Positive Adults
- Prevention and Prophylaxis for Occupational Exposure to HIV and Other Blood Borne Pathogens
- Prophylaxis and Treatment of Opportunistic Infections in Patients with HIV Disease
- HIV in Pregnancy - Preventing Perinatal Transmission
- Rapid Diagnostic HIV Testing
- **Non-Occupational Post-Exposure Prophylaxis (new)**



To schedule a free 1-hour HIV medical education program at your health care site on any of the topics in the HIV/AIDS Medical Update Series, contact Debra Bottinick at (609) 921-6622 or dbottinick@academycme.org.

Now available online!

- Rapid Diagnostic HIV Testing
- HIV in Pregnancy: Preventing Perinatal transmission - Care for Mother and Baby

Earn .5 CME/CE credit for successfully completing each of these audio slide presentations.

For Rapid Diagnostic HIV Testing go to:

http://www.academycme.org/cme/rdh/index.html

For HIV in Pregnancy: Preventing Perinatal Transmission go to:

http://www.academycme.org/cme/hprg/index.html

Sponsors: Center for Continuing and Outreach Education-Division of AIDS Education at UMDNJ, and the American Academy of CME, Inc., with funding from the NJ Department of Health & Senior Services, Division of HIV/AIDS Services.

Internet Resources

Information and Guidelines

NJ Department of Health & Senior Services Division of HIV/AIDS Services (DHAS)

www.state.nj.us/health/aids/aidsprv.htm

NJ HIV/AIDS Semi-annual Newsletter (statistical report); policies, and clinical guidelines for HIV/AIDS care and services in New Jersey.

New Jersey rapid testing site: FAQS, locations, and articles

www.state.nj.us/health/aids/rapidtesting

US Dept. of Health & Human Services

www.aidsinfo.nih.gov

1-800-HIV -0440 (1-800-448-0440)

A service of the US Department of Health and Human Services offering HIV/AIDS treatment guidelines, other information on prevention, treatment, and research.

National Institutes of Health-sponsored searchable database of clinical trials:

http://clinicaltrials.gov

Centers for Disease Control (CDC) Division of HIV/AIDS Prevention

HIV/AIDS research, surveillance reports [2004 summary now available], funding announcements, research and reporting software, surveillance/ epidemiology slide sets.

www.cdc.gov/hiv/hivinfo.htm#WWW

Rapid Testing: www.cdc.gov/hiv/rapid_testing

MMWR [Morbidity and Mortality Weekly reports]:

www.cdc.gov/hiv/pubs/mmwr.htm

CDC National Prevention Information Network (NPIN)

HIV, STD, and TB-related news summaries, funding announcements, materials, conference and satellite broadcast announcements.

www.cdcnpin.org

FDA MedWatch

Updated reports on medication interactions and warnings: 1-800-FDA-1088. Subscribe to e-bulletin:

www.fda.gov/medwatch/elist.htm

National HIV/AIDS Clinicians' Consultation Center

http://www.ucsf.edu/hivcntr

Consultation on antiretroviral therapy, drug resistance, opportunistic infection prophylaxis and treatment, laboratory evaluation; occupational exposure, perinatal intervention.

Warmline: 800-933-3413.

National Clinicians' Post-Exposure Prophylaxis Hotline

(PEPline): 888-448-4911 (888-HIV-4911)

National Perinatal HIV Consultation and Referral Service:

888-448-8765 (888-HIV-8765)

Training and Education

University of Medicine & Dentistry of NJ Center for Continuing and Outreach Education Division of AIDS Education

www.umdnj.edu/ccoe/aids

Conferences, training programs, and online education for HIV/AIDS health and social service professionals. Online registration available.

Free online CME. Topics include:

- Recommendations to Reduce the Risk of Occupational HIV Transmission After an Exposure Incident
- Update on HIV and Hepatitis C Virus Co-Infection
- Treatment of Tuberculosis in Patients Infected with HIV
- Rapid Diagnostic Testing for HIV (updated 6/06)
- Impact of the New Guidelines for the Use of Antiretroviral Agents in HIV-1- Infected Adults and Adolescents
- Community Based HIV Treatment Adherence Support; NJ Standards of Practice

NY/ NJ AETC

New York/ New Jersey regional training calendar, directory of HIV treatment and support resources; links and downloads for clinician support tools and treatment references including training slide sets and wall charts.

www.nynjaetc.org

AIDS Education and Training Centers (AETC) National Resource Center

www.aids-etc.org

HIV treatment guidelines and news, training materials and curricula, evaluation tools, and links to all AETCs. Daily HIV/AIDS Treatment News [multi-source] and Clinical Information Resources including PDA tools.

STD/HIV Prevention Training Centers (PTC)

Medical: www.nyc.gov/html/doh/html/std/ptc.shtml

Behavioral: www.urmc.rochester.edu/chbt

Addiction Technology Transfer Center (ATTC)

[SAMHSA funded] training, addiction treatment news

Northeast ATTC: www.neattc.org

Title X Family Planning Regional Training Center (RTC)

[DHHS/OPA funded] training:

www.cicatelli.org/titlex/home.htm

SAVE THE DATES!

Mobilizing Against the HIV/AIDS Crisis Among African Americans Satellite Broadcast

Thursday, November 16th, 2006, 12:30 PM-3:00 PM

Where: Viewing sites at NJN in Newark and Trenton.

For more information and to register:
call Michelle Thompson: (973) 972-1293 or
e-mail: ccthomps@umdnj.edu.

17th Annual HIV Medical Update

Wednesday, December 6, 2006
Crowne Plaza Hotel (formerly The Hilton) - Cherry Hill, NJ

Early Registration $40.00 until 11/22/06
$50.00 after 11/22/06

Register Online at www.umdnj.edu/ccoe or
call (800) 227-4852, option 3 [course code 07HL01]

Information: Michelle Thompson: (973) 972-1293 or
ccthomps@umdnj.edu

Reducing Perinatal HIV Transmission in NJ

Friday, March 23, 2007
NJ Hospital Association Conference Center, Princeton NJ

Details will follow in future issues
of AIDSLine and at:
www.umdnj.edu/ccoe

Call for Posters!
See pages 20 - 21

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