Now Legal: HIV Testing for Minors without Parental or Guardian Consent

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On January 12, 2006, former Governor Richard J. Codey signed into law Senate Bill 2481. This legislation permits a minor, who is at least 13 years of age, to consent to the provision of medical or surgical care (including testing) if he or she believes that they may be infected with HIV. This law, which took effect immediately on January 12, 2006, amends N.J.S.A. 9:17 A-4 and thus, permits minors (at least 13 years of age) to be tested for HIV without parental or guardian consent. Therefore, any agency or program that offers HIV counseling and testing may provide an HIV test to a minor (who is at least 13 years of age), and do so without that minor obtaining the consent of a parent or guardian.

As with all persons seeking HIV counseling and testing, counselors must assess readiness for testing and receiving results. Counselors are encouraged to consider the unique characteristics of adolescence including feelings of invincibility, a compromised ability to anticipate consequences, and more frequent emotional reactions than their adult counterparts.

It is recommended that counselors expand specific aspects of the counseling session. Counselors should explore and expand communication to address preparedness for results; feelings and concerns about results and treatment options; and implementation of follow-up plans. Increased involvement in incorporating parent or guardian involvement and providing personalized assistance in accessing needed services should be anticipated. Counselors should be able to provide information on additional resources available in your community that specialize in adolescent care (i.e., physicians, therapists, mentors, prevention programs).

Because these are adolescents, additional treatment resources are available through the New Jersey Department of Health and Senior Services Statewide Family HIV Care Network. Other physicians with experience treating adolescents with HIV/AIDS may also be available in your community.
RECOMMENDATIONS TO REDUCE THE RISK OF OCCUPATIONAL HIV TRANSMISSION AFTER AN EXPOSURE INCIDENT

TARGET AUDIENCE
This activity is designed for physicians and nurses, and for other health care professionals who are involved in the care of individuals with HIV infection.

STATEMENT OF NEED
The CDC published Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis, [MMWR 2005;54 (No. RR-9)] on September 30, 2005. The CDC explained the need for new guidelines in this document as a concern for clinicians who treat health care workers and those who provide HIV medical care, who are essential consultants in selection of appropriate treatment regimens:

This report updates U.S. Public Health Service recommendations for the management of healthcare personnel (HCP) who have occupational exposure to blood and other body fluids that might contain human immunodeficiency virus (HIV). Although the principles of exposure management remain unchanged, recommended HIV postexposure prophylaxis (PEP) regimens have been changed. This report emphasizes adherence to HIV PEP when it is indicated for an exposure, expert consultation in management of exposures, follow-up of exposed workers to improve adherence to PEP, and monitoring for adverse events, including seroconversion. To ensure timely postexposure management and administration of HIV PEP, clinicians should consider occupational exposures as urgent medical concerns.

The goal of this report is to provide recommendations for guiding clinical practice in managing PEP for health-care personnel (HCP) with occupational exposure to HIV.

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

• Identify high-risk occupational HIV exposures for health care workers.
• Describe antiretroviral regimens to reduce the risk of occupational HIV transmission.
• Describe the appropriate use of HIV postexposure prophylaxis (PEP).
• List situations for which expert consultation in the management of occupational exposures is recommended.

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.

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This activity was reviewed for relevance, accuracy of content, balance of presentation, and time required for participation by BeverlyAnn Collins, RN, MS; James W. Henry, BSN, Debbie M. Winters, MSN, APRN-BC, AACRN, and Patricia M. Kloser, MD, MPH.

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

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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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Expiration date: Credit for this activity will be provided through June 2007
**Learning Objectives:**

The goal of this report is to provide recommendations for guiding clinical practice in managing postexposure prophylaxis (PEP) for health-care personnel (HCP) with occupational exposure to HIV. Upon completion of this educational activity, the reader should be able to:

1. Identify high-risk occupational HIV exposures for health care workers.
2. Describe antiretroviral regimens to reduce the risk of occupational HIV transmission.
3. Describe the appropriate use of HIV PEP.
4. List situations for which expert consultation in the management of occupational exposures is recommended.

**Abstract**

HIV infection is an occupational risk for health care workers. To assist these health care workers, the United States Public Health Service (PHS) issued updated recommendations for post-exposure chemoprophylaxis in a Recommendations and Reports supplement to the Morbidity and Mortality Weekly Report (September 30, 2005, Vol. 54, No. RR-9).

**Introduction**

The transmission of bloodborne pathogens is an occupational hazard for health care workers. Nationally, as of December 31, 2002, 57 health care workers had become HIV infected as a result of an occupational exposure. Twenty-six of these workers have developed AIDS. The 57 health care workers include: 24 nurses, 19 laboratory technicians, 6 physicians, 2 surgical technicians, 2 housekeeping/maintenance workers, 1 dialysis technician, 1 respiratory therapist, 1 health aide/attendant, and 1 embalmer/morgue technician. The most common route of exposure for occupational HIV transmission is percutaneous. Forty-eight of the seroconversions occurred as a result of a percutaneous exposure, 5 occurred through a mucocutaneous exposure (mucous
membrane and/or skin exposure), 2 occurred due to a combined percutaneous and mucocutaneous exposure, and for two, the route of exposure was unknown. The purpose of this paper is to describe the updated recommendations from the CDC for medical intervention to reduce the risk of occupational HIV transmission after an exposure incident. Changes from the 2001 recommendations include:

1) Modification and expansion of the list of antiretroviral medications that can be considered for use as PEP

2) Emphasis on prompt management of occupational exposures

3) Selection of tolerable regimens

4) Attention to potential drug interactions involving drugs that could be included in HIV PEP regimens and other medications

5) Consultation with experts for post-exposure management strategies (especially determining whether an exposure has actually occurred) and selection of HIV PEP regimens

6) The use of HIV rapid testing, and counseling and follow-up of exposed personnel.

In addition to HIV, health care workers should be evaluated for potential hepatitis B and hepatitis C transmission after an exposure incident.

In order to reduce or eliminate the hazards of occupational exposure to blood or other potentially infectious materials (OPIM), the federal Occupational Safety and Health Administration (OSHA) promulgated the “Occupational Exposure to Bloodborne Pathogens” Standard (29 CFR 1910.1030) in 1991. The Standard requires that the employer must implement an exposure control plan for the worksite with details on employee protection measures. The Plan must also describe how an employer will use a combination of engineering controls (including the use of safer needle devices) and work practice controls; ensure the use of personal protective clothing and equipment; provide training, medical surveillance, hepatitis B vaccinations, and warning signs and labels, among other provisions.

**Risk of HIV Transmission**

The average risk of HIV infection from all types of percutaneous exposures to HIV-infected blood is 0.3 percent. The Centers for Disease Control and Prevention (CDC) conducted a case-control study to determine the risk of HIV infection from different types of percutaneous exposures. This case control study showed that the risk of HIV infection exceeded 0.3 percent for exposures that involved a deep injury to the health care worker; visible blood on the device that caused the injury; a device had been placed in the source-patient’s vascular system, (e.g., a needle used for phlebotomy); or a source patient died as a result of AIDS within 60 days postexposure.

The increased risk associated in these scenarios may be related to exposure to larger volumes of blood, or to blood containing a higher titer of the HIV virus. However, the utility of viral load measurements from the source-patient as a surrogate for estimating the viral titer for assessing transmission risk is unknown. HIV transmission from those with a viral load below detectable limits has been reported in one health care worker seroconversion and in instances of mother-to-infant transmission.

The average risk of HIV infection following a mucous membrane or skin exposure is less than the risk associated with a percutaneous exposure. The average risk of HIV infection after a mucous membrane exposure is 0.09 percent. The average risk of HIV infection after a skin exposure is less than 0.09 percent. The risk for skin exposure may be increased if skin contact is prolonged, if contact involved an extensive area of the skin, if the integrity of the skin is not intact, or if the exposure involves a higher titer of HIV.

**Follow Up After an Exposure Incident**

One of the requirements of the OSHA Bloodborne Pathogens Standard is that employers must provide designated employees (e.g., health care workers) with a system for prompt evaluation, counseling, and follow-up after an exposure incident. First aid should be administered immediately after an exposure.

- Puncture wounds and exposure to non-intact skin (dermatitis, hangnails, abrasions, chafing, acne, etc) should be washed with soap and water.
- Exposure to oral and nasal mucosa should be decontaminated by flushing with water.
- Eyes should be irrigated with clean water and saline or sterile irrigants that are designed for flushing eyes.
- The exposure should be reported to the person or department, (e.g., employee health, infection control), which is responsible for managing exposures.

Employee HIV antibody tests should be performed at baseline and periodically for at least six months postexposure, e.g., 6 weeks, 12 weeks, and six months. HIV testing also should be performed on any health care worker who has an illness compatible with an acute retroviral syndrome, regardless of the interval since the exposure. HIV antibody testing using enzyme immunoassay (EIA) should be used to monitor for seroconversion. The routine use of direct assays, (e.g., HIV antigen EIA or polymerase chain reaction for HIV RNA), to detect infection in health care workers is generally not recommended. The reliability of HIV RNA testing to detect very early infection has not been determined and it is not FDA approved for this purpose. The employee should be counseled on precautions to prevent secondary transmission of HIV.

Testing to determine the HIV status of an exposure source should be performed as soon as possible. The exposure
source should receive pre and post-test counseling and give consent for HIV testing. A Food and Drug Administration (FDA) approved rapid HIV-antibody test kit should be considered for use in this situation, particularly if testing by EIA cannot be completed in 24-48 hours. Five rapid HIV tests have been approved by the United States Food and Drug Administration (FDA) for commercial use: the Single Use Diagnostic System for HIV-1, (SUDS, Abbott Laboratories, Abbott Park, IL—no longer marketed), OraQuick® HIV-1 and the OraQuick® Advance HIV-1/HIV-2, (OraSure Technologies, Bethlehem, PA), Reveal™ G2 Rapid HIV-1 Antibody Test (MedMira Laboratories, Halifax, Nova Scotia), Uni-Gold™ Recombigen® HIV (Trinity Biotech plc - Wicklow, Ireland), and Multispot HIV-1/HIV-2 (Bio-Rad Laboratories, Hercules, CA). Additional rapid HIV tests are under consideration by the FDA. Repeatedly, reactive results by EIA or rapid HIV-antibody tests are considered to be highly suggestive of infection, whereas a negative result is an excellent indicator of the absence of HIV antibody. Confirmation of a reactive result by Western Blot or immunofluorescent antibody is not necessary to make initial decisions about postexposure management but should be done to complete the testing process and before informing the source person.²

**Postexposure Prophylaxis**

In some instances, appropriate postexposure management includes antiretroviral agents for PEP. A multinational study found that PEP with zidovudine (ZDV) decreased the risk of HIV infection, following percutaneous exposure by 81 percent.³ However, failures have occurred. Data published in the 2001 recommendations indicated that in 16 cases ZDV was used as monotherapy, in two cases ZDV was used with didanosine (ddI), and in three cases > 3 drugs were used for PEP. Resistance testing of virus from the source patient was done in seven instances and in four, the HIV infection transmitted was found to have decreased sensitivity to ZDV and/or other drugs used for PEP. Subsequently an additional report of an occupational HIV seroconversion despite combination HIV PEP has been published.⁴

**Recommendations**

Although these recommendations represent the most recent United States Public Health Service recommendations for PEP, they are subject to change. PEP is not recommended for all types of occupational exposure to HIV because the majority of occupational exposures do not result in HIV transmission. The need for PEP is based on the risk for HIV infection after different types of exposure and on limited data regarding efficacy and toxicity of PEP.⁴

PEP should be initiated as soon as possible. The interval within which PEP should be initiated for optimal efficacy is not known. Although animal studies suggest that PEP probably is substantially less effective when started more than 24-36 hours postexposure, the interval after which no benefit is gained from PEP for humans is undefined. Therefore, if appropriate for the exposure, PEP should be started even when the interval since exposure exceeds 36 hours. Initiating therapy after a longer interval (e.g., one-week) might be considered for exposures that represent an increased risk for transmission. The optimal duration of PEP is unknown. Because four weeks of ZDV appeared protective in occupational and animal studies PEP probably should be administered for four weeks, if tolerated.³ ⁴

To assist with the initial management of an HIV exposure, healthcare facilities should have drugs for an initial PEP regimen selected and available for use. Because PEP is potentially toxic, its use is not justified for exposures that pose a negligible risk for transmission. Two regimens for PEP are suggested: a “basic” two-drug regimen that should be appropriate for most HIV exposures, and an “expanded” three-drug regimen that should be used for exposures that pose an increased risk for transmission. When possible, the regimens should be implemented in consultation with persons who have expertise in antiretroviral treatment and HIV transmission.⁴

All antiretroviral agents have been associated with side effects. Because side effects are frequent and particularly because they are cited as a major reason for not completing PEP regimens as prescribed, the selection of regimens should be heavily influenced toward those that are tolerable for short-term use. Therefore, the toxicity profile of antiretroviral agents, including the frequency, severity, duration, and reversibility of side effects, is an important consideration in selection of an HIV PEP regimen. The majority of data concerning adverse events have been reported primarily for persons with established HIV infection receiving prolonged antiretroviral therapy and therefore might not reflect the experience of uninfected persons who take PEP. Anecdotal evidence from clinicians knowledgeable about HIV treatment indicates that antiretroviral agents are tolerated more poorly among HCP taking HIV PEP than among HIV-infected patients on antiretroviral medications.⁴

Most HIV exposures will warrant a two-drug regimen, using two Nucleoside Reverse Transcriptase Inhibitors (NRTIs) or one NRTI and one Nucleotide Reverse Transcriptase Inhibitor (NtRTI). Combinations that can be considered for PEP include: ZDV and 3TC or emtricitabine (FTC); dd4T and 3TC or FTC; and tenofovir (TDF) and 3TC or FTC. In the previous PHS guidelines, a combination of dd4T and ddI was considered one of the first-choice PEP regimens; however, this regimen is no longer recommended because of concerns about toxicity (especially neuropathy and pancreatitis) and the availability of more tolerable alternative regimens.³ See Tables 1 and 2 on p. 6.

The addition of a third (or even a fourth) drug should be considered for exposures that pose an increased risk for transmission or that involve a source in whom antiretroviral drug resistance is likely. Previously, IDV, nelfinavir (NFV), EFV, or abacavir (ABC)
### Table 1. Recommended HIV Postexposure Prophylaxis for Percutaneous Injuries

<table>
<thead>
<tr>
<th>Infection status of source</th>
<th>Exposure type</th>
<th>HIV-positive class 1~</th>
<th>HIV-positive class 2~</th>
<th>Source of unknown HIV status~</th>
<th>Unknown source^</th>
<th>HIV-negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Less severe«</td>
<td>Recommend basic 2-drug PEP</td>
<td>Recommend expanded 3-drug PEP</td>
<td>Generally, no PEP warranted, however consider basic 2-drug PEP** for source with HIV risk factors++</td>
<td>Generally, no PEP warranted, however consider basic 2-drug PEP** in settings where exposure to HIV-infected persons is likely</td>
<td>No PEP warranted</td>
</tr>
<tr>
<td></td>
<td>More severe&gt;&gt;</td>
<td>Recommend expanded 3-drug PEP</td>
<td>Recommended expanded 3-drug PEP</td>
<td>Generally, no PEP warranted, however consider basic 2-drug PEP** for source with HIV risk factors++</td>
<td>Generally, no PEP warranted, however consider basic 2-drug PEP** in settings where exposure to HIV-infected persons is likely</td>
<td>No PEP warranted</td>
</tr>
</tbody>
</table>

* HIV positive, Class 1 - asymptomatic HIV infection or known low viral load (e.g., <1,500 RNA copies/mL). HIV positive, Class 2 - symptomatic HIV infection, AIDS, acute serocoversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of postexposure prophylaxis (PEP) should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.

~ Source of unknown HIV status (e.g., deceased source person with no samples available for HIV testing).

^ Unknown source (e.g., a needle from a sharps disposal container).

« Less severe (e.g., solid needle or superficial injury).

++ If PEP is offered and taken and the source is later determined to be HIV negative, PEP should be discontinued.

>> More severe (e.g., large-bore hollow needle, deep puncture, visible blood on device, or needle used in patient's artery or vein).

### Table 2. Recommended HIV Postexposure Prophylaxis for Mucous Membrane Exposures and Nonintact Skin

<table>
<thead>
<tr>
<th>Infection status of source</th>
<th>Exposure type</th>
<th>HIV-positive class 1*</th>
<th>HIV-positive class 2*</th>
<th>Source of unknown HIV status~</th>
<th>Unknown source#</th>
<th>HIV-negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Small volume φ</td>
<td>Consider basic 2-drug PEP~~</td>
<td>Recommend expanded 3-drug PEP</td>
<td>Generally, no PEP warranted ++</td>
<td>Generally, no PEP warranted</td>
<td>No PEP warranted</td>
</tr>
<tr>
<td></td>
<td>Large volume ›</td>
<td>Recommend expanded 3-drug PEP</td>
<td>Recommended expanded 3-drug PEP</td>
<td>Generally, no PEP warranted, however consider basic 2-drug PEP** for source with HIV risk factors++</td>
<td>Generally, no PEP warranted, however consider basic 2-drug PEP** in settings where exposure to HIV-infected persons is likely</td>
<td>No PEP warranted</td>
</tr>
</tbody>
</table>

* HIV positive, Class 1 - asymptomatic HIV infection or known low viral load (e.g., <1,500 RNA copies/mL). HIV-Positive, Class 2 - symptomatic HIV infection, AIDS, acute serocoversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of postexposure prophylaxis (PEP) should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.

~ Source of unknown HIV status (e.g., deceased source person with no samples available for HIV testing)

φ Small volume (e.g., a few drops).

# Unknown source (e.g., splash from inappropriately disposed blood).

** The designation “consider PEP” indicates that PEP is optional and should be an individualized decision between the exposed person and the treating clinician.

++ If PEP is offered and taken and the source is later determined to be HIV negative, PEP should be discontinued.

› Large volume (e.g., major blood splash)
were recommended as first-choice agents for inclusion in an expanded PEP regimen. 4

The PHS now recommends that expanded PEP regimens be protease inhibitor (PI)-based. The PI preferred for use in expanded PEP regimens is lopinavir/ritonavir (LPV/RTV). Other PIs acceptable for use in expanded PEP regimens include atazanavir, fosamprenavir, RTV-boosted IDV, RTV-boosted SQV, or NVP (Appendix to guidelines). Although side effects are common with NNRTIs, EFV may be considered for expanded PEP regimens, especially when resistance to PIs in the source person’s virus is known or suspected. Caution is advised when EFV is used in women of childbearing age because of the risk of teratogenicity. 4

Drugs that may be considered as alternatives to the expanded regimens, with warnings about side effects and other adverse events, are EFV or PIs as noted in the Appendix in combination with ddI and either 3TC or FTC. The fusion inhibitor enfuvirtide (T20) has theoretic benefits for use in PEP because its activity occurs before viral-host cell integration; however, it is not recommended for routine HIV PEP because of the mode of administration (subcutaneous injection twice daily). Furthermore, use of T20 has the potential for production of anti-T20 antibodies that cross react with HIV gp41. This could result in a false-positive, enzyme immunoassay (EIA) HIV antibody test among HIV-uninfected patients. A confirmatory Western blot test would be expected to be negative in such cases. T20 should only be used with expert consultation. 4

Antiviral drugs not recommended for use as PEP, primarily because of the higher risk for potentially serious or life-threatening adverse events, include ABC, delavirdine, ddC, and, as noted previously, the combination of ddI and d4T. NVP should not be included in PEP regimens except with expert consultation because of serious reported side effects, including hepatotoxicity (with one instance of fulminant liver failure requiring liver transplantation), rhabdomyolysis, and hypersensitivity syndrome. 4

Because of the complexity of selection of HIV PEP regimens, consultation with persons having expertise in antiretroviral therapy and HIV transmission is strongly recommended. Selection of the PEP regimen should consider the comparative risk represented by the exposure and information about the exposure source, including history of and response to antiretroviral therapy based on clinical response, CD4+ T-cell counts, viral load measurements, and current disease stage. When the source person’s virus is known or suspected to be resistant to one or more of the drugs considered for the PEP regimen, the selection of drugs to which the source person’s virus is unlikely to be resistant is recommended; expert consultation is advised. If this information is not immediately available, initiation of PEP, if indicated, should not be delayed; changes in the PEP regimen can be made after PEP has been started, as appropriate. Reevaluation of the exposed person should be considered within 72 hours postexposure, especially as additional information about the exposure or source person becomes available. 4

**USE OF PEP WHEN HIV INFECTION STATUS OF SOURCE PERSON IS UNKNOWN**

If the source person’s HIV infection status is unknown at the time of exposure, use of PEP should be decided on a case-by-case basis, after considering the type of exposure and the clinical and/or epidemiologic likelihood of HIV infection in the source (Tables 1 and 2). If these considerations suggest a possibility for HIV transmission, then initiating a two-drug regimen is recommended. Once the source’s HIV test results are obtained, the need for PEP and medications can be reevaluated. The following are recommendations regarding HIV postexposure prophylaxis:

- If indicated, start PEP as soon as possible after an exposure.
- Reevaluation of the exposed person should be considered within 72 hours postexposure, especially as additional information about the exposure or source person becomes available.
- Administer PEP for 4 weeks, if tolerated.
- If a source person is determined to be HIV-negative, PEP should be discontinued. 4

**PEP FOR PREGNANT HEALTH CARE WORKERS**

If the exposed person is pregnant, the evaluation of risk of infection and need for PEP should be approached as with any other person who has had an HIV exposure. However, the decision to use any antiretroviral drug during pregnancy should involve discussion between the woman and her health care provider(s) regarding the potential benefits and risks to her and her fetus. 4

Certain drugs should be avoided in pregnant women. Because teratogenic effects were observed in primate studies, (efavirenz) EFV is not recommended during pregnancy. Reports of fatal lactic acidosis in pregnant women treated with a combination of d4T and ddI have prompted warnings about these drugs during pregnancy. Because of the risk of hyperbilirubinemia in newborns, indinavir (IDV) should not be administered to pregnant women shortly before delivery. 4

**MONITORING AND SIDE EFFECTS**

If PEP is used, drug-toxicity monitoring needs to be performed. This should include a complete blood count and renal and hepatic chemical function tests at baseline and two weeks after starting PEP. Monitoring for hyperglycemia should be included for PEP regimens that include a protease inhibitor. If IDV is included in the regimen, monitoring for crystalluria, hematuria, hemolytic anemia, and hepatitis also should be performed. If toxicity is noted, dose reduction or drug substitution should
be considered with expert consultation. Further diagnostic studies may be indicated. Health care workers who become HIV-infected should receive appropriate medical care. Side effects may cause difficulty with adherence to PEP. Common symptoms associated with many of nucleoside reverse transcriptase inhibitors (NRTIs) are chiefly gastrointestinal such as nausea or diarrhea. Other common symptoms include headache, malaise, fatigue, or insomnia. However, serious side effects, including nephrolithiasis, hepatitis, and pancytopenia have been reported with combination PEP. These symptoms often can be managed without changing the regimen by prescribing antiemetic and antiemetic or other medications that target specific symptoms. In other situations, modifying the dose interval, e.g., administering a lower dose more frequently throughout the day, as recommended by the manufacturer, may help promote adherence to the regimen.

All the FDA-approved protease inhibitors (PI) have potentially serious drug interactions. Therefore, careful evaluation of interactions with concomitant medications is necessary prior to prescribing a PI.

Healthcare workers often fail to complete the recommended regimen because they experience side effects (e.g., nausea or diarrhea). These symptoms often can be managed with antiemetic and antiemetic agents or other medications that target specific symptoms without changing the regimen. In other situations, modifying the dose interval (i.e., administering a lower dose more frequently throughout the day, as recommended by the manufacturer) might facilitate adherence to the regimen. Serious adverse events should be reported to FDA’s MedWatch program.

The United States Public Health Service recommendations for PEP are intended to provide guidance to physicians. Local experts can modify the recommendations on a case-by-case basis. Whenever possible, expert consultation is recommended.

**REFERENCES:**


**CASE REVIEW**

**Occupational Exposure to HIV: Reducing the Risks of Transmission**

A 27-year-old medical assistant (MA) presents to Urgent Care for evaluation of a needlestick injury. The injury occurred two days prior, while testing a 35-year-old known HIV+ male with a diabetic lancet. To her knowledge, the patient has never been treated for HIV and is unaware of his CD4+ count and VL. The lancet was visibly bloody, pierced her glove and caused her to bleed.
1. What is her risk for contracting HIV?
   a. Low risk, low volume exposure to a known HIV+ source patient
   b. High risk, high volume exposure to a known HIV+ source patient
   c. Low risk, high volume exposure to a known HIV+ source patient
   d. High risk, low volume exposure to a known HIV+ source patient

   The source patient is known to be HIV+ and the device used on this patient was visibly contaminated with blood. The medical assistant did in fact pierce her finger with the bloody lancet and this caused her to bleed. Because the source patient is known HIV+ this is (d) a high-risk exposure with low blood volume

2. Which of the following statements is TRUE about PEP in this instance?
   a. PEP is not indicated because too much time has elapsed since the needle stick injury.
   b. PEP is warranted in this case and a 2-drug regimen should be initiated as soon as possible.
   c. An evaluation of the source patient’s resistance pattern should be obtained before initiating PEP for this injury.
   d. More information is needed before a decision to start PEP can be made.

   Ideally, PEP should be initiated as soon after the injury as possible and optimally within the first 36 hours. Studies however have not determined at which point after exposure PEP is no longer effective. Use of the source patient’s viral load and resistance pattern are not prerequisites for starting PEP. In this case, a standard two-drug regimen (b) should be initiated. Should information about the source patient’s status be determined at a later date, the regimen can be changed as appropriate.

3. Which of the following would be an appropriate basic two-drug PEP regimen to prescribe for this patient?
   a. Zidovudine (Retrovir) 300 mg twice daily + Lamivudine (Epivir) 150 mg twice daily
   b. Zidovudine (Retrovir) 300 mg twice daily + Indinavir (Crixivan) 800 mg every eight hours
   c. Zidovudine (Retrovir) 300 mg twice daily + Nevirapine (Viramune) 200 mg twice daily
   d. Combivir (Zidovudine 300 mg + Lamivudine (Epivir) 150 mg) + Efavirenz (Sustiva) 600 mg at hour of sleep

   The most appropriate basic two-drug regimen in this case would be (a) Zidovudine (Retrovir) + Lamivudine (Epivir). The use of a PI (Protease Inhibitor) with Zidovudine is inappropriate. Nevirapine is not recommended for use as PEP. Efavirenz (Sustiva) should be avoided during pregnancy and is not a part of the basic regimen. Combivir and Efavirenz are a three-drug regimen.

   New information: After extensive counseling, you recommend that the medical assistant take the basic two-drug regimen, but before she leaves, the triage nurse informs you that the following information about the source patient has been obtained from the primary care physician:
   - CD4+ count two months ago 450 cells/mm3: CD4+ nadir 280 cells/mm3
   - Viral load two months ago 60,000 copies/mL
   - The patient has never had an OI
   - The patient is not naïve to therapy: for the past year he has been on Zidovudine (Retrovir), Lamivudine (Epivir), Ritonavir (Norvir), and Indinavir (Crixivan)

4. How does this information affect the PEP regimen you prescribed?
   a. No change, the standard basic two-drug PEP regimen is appropriate for this patient.
   b. A high viral load in the source patient suggests that he is either non-compliant or resistant to the current treatment regimen and expert advice may be helpful.
   c. The PEP regimen should be discontinued until resistance testing results are obtained.
   d. Discontinue the current PEP regimen and begin ddi + tenofovir + efavirenz immediately.

   A high viral load in the source patient suggests that either the patient has not been adherent to the current treatment or he has developed resistance to this regimen. The time required to evaluate resistance testing in this patient is too long to make a determination for PEP regimen for the injured patient. Starting a three-four-drug PEP regimen (b) should be guided by expert advice. The use of ddi, tenofovir and efavirenz is no longer recommended as appropriate ART treatment.

5. Which of the following is appropriate post-exposure follow-up HIV testing for this patient?
   a. 6 weeks 3 months, 6 months
   b. 6 weeks, 3 months, 6 months, 12 months
   c. Every three months along with CD4+ and VL counts
   d. Every six weeks

   CDC recommends (a) HIV Ab testing for 6 months following exposure, (e.g. at 6 weeks, 3 months, 6 months). If the source patient is co-infected with HIV and HCV, however, extended HIV Ab testing is recommended at 12 months if the health care worker contracts Hepatitis C.

   To obtain continuing education credit for this activity, please turn the page for self-assessment test, registration, and evaluation forms.

Case material from the Northwest AIDS Education and Training Center (NWAETC), as posted on the AETC National Resource Center website, www.aids-etc.org for educational use; adapted by Brenda J. Christian, M.Ed, PA-C, of the UMDNJ-CCOE-Division of AIDS Education for this article.
SELF-ASSESSMENT TEST

Recommendations to Reduce the Risk of Occupational HIV Transmission After an Exposure Incident

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/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 must be included in the exposure control plan required by the federal Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens” Standard (29 CFR 1910.1030)?
   A. Provide safer needle devices
   B. Offer hepatitis B vaccinations
   C. Conduct medical surveillance
   D. All of the above

2. The recommended length of time for occupational postexposure prophylaxis for a healthcare worker is:
   A. 4 hours
   B. 4 days
   C. 4 weeks
   D. 4 months

3. Which of the following is the highest risk exposure for HIV transmission?
   A. Eye splash while suctioning an incubated patient
   B. Intraoperative cut from a scalpel
   C. Needlestick injury after phlebotomy
   D. Wound drainage on non-intact skin

4. Which of the following classes of antiretroviral agents is recommended for an expanded PEP regimen?
   A. Fusion inhibitors
   B. Non-nucleoside reverse transcriptase inhibitors
   C. Nucleoside reverse transcriptase inhibitors
   D. Protease inhibitors

5. Postexposure prophylaxis of zidovudine (AZT, ZDV) plus lamivudine (3TC) would be recommended after a health care worker has a needlestick exposure to an asymptomatic HIV infected patient, if the needlestick occurred:
   A. After removing an arterial line
   B. Prior to performing phlebotomy
   C. Prior to starting an IV
   D. After suturing a wound

6. Which of the following tests is recommended to determine the HIV status of an exposure source as soon as possible?
   A. CD4 T cell count
   B. Rapid HIV test
   C. Viral Load for HIV
   D. Western blot

7. Following an occupational exposure to HIV, employees should have HIV antibody tests performed at baseline and periodically until which of the following times?
   A. 3 months
   B. 6 months
   C. 9 months
   D. 12 months

8. Which antiretroviral medication is contraindicated for use by pregnant health care personnel?
   A. Efavirenz.
   B. Zidovudine.
   C. Nelfinavir.
   D. Tenofovir.

9. To monitor drug-toxicity of a PEP regimen that includes AZT and 3TC, which of the following should be assessed?
   A. Crystalluria
   B. Hemolytic anemia
   C. Hyperglycemia
   D. Renal function

10. Which of the following first aid scenarios following an exposure incident is recommended?
    A. Eyes should be irrigated with clean water and saline or sterile irrigants that are designed for flushing eyes.
    B. Exposure to oral and nasal mucosa should be decontaminated by flushing with water
    C. Puncture wounds and exposure to non-intact skin (dermatitis, hangnails, abrasions, chafing, acne, etc) should be washed with soap and water.
    D. All of the above
University of Medicine and Dentistry of New Jersey  
Center for Continuing and Outreach Education  

Recommendations to Reduce the Risk of Occupational HIV Transmission After an Exposure Incident

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 reverse side, and record your test answers below
(3) Send the registration and evaluation forms to:
   UMDNJ-Center for Continuing and Outreach Education
   via mail: PO Box 1709, Newark, NJ 07101-1709
   via fax: (973) 972-7128
(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.

10. A  B  C  D

REGISTRATION

First Name_________________________M.I.______ Last Name______________________________Degree__________________

Daytime Phone #: __________________ Evening Phone #: __________________

Fax #: _____________________________ E-mail __________________________

Preferred Mailing Address:     ___Home     ___Business
Address______________________________________________________________________________

City_______________________________State___________Zip Code______________________________

Affiliation, Specialty________________________

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

Signature_________________________________________ Date________________________

Release date: March 2006  
Expiration date: Credit for this activity will be provided through June 2007

UMDNJ-Center for Continuing and Outreach Education  
PO Box 1709, Newark, NJ 07101-1709
Phone: 973-972-4267 or 1-800-227-4852  
Fax: 973-972-7128

CE Activity Code: 07HCo2- DE01
University of Medicine and Dentistry of New Jersey  
Center for Continuing and Outreach Education  

Recommendations to Reduce the Risk of Occupational HIV Transmission After an Exposure Incident  

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, I am better able to:  

<table>
<thead>
<tr>
<th>Objective</th>
<th>Strongly Agree</th>
<th>Strongly Disagree</th>
</tr>
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<tbody>
<tr>
<td>1. Identify high-risk occupational HIV exposures for health care workers</td>
<td>5</td>
<td>4</td>
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<tr>
<td>2. Describe antiretroviral regimens to reduce the risk of occupational HIV transmission.</td>
<td>5</td>
<td>4</td>
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<tr>
<td>3. Describe the appropriate use of HIV postexposure prophylaxis (PEP).</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>4. List situations for which expert consultation in the management of occupational exposures is recommended.</td>
<td>5</td>
<td>4</td>
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</tbody>
</table>

OVERALL EVALUATION:  

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Agree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>The information presented increased my awareness/understanding of the subject.</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>The information presented will influence how I practice.</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>The information presented will help me improve patient care.</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>The faculty demonstrated current knowledge of the subject.</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>The program was educationally sound and scientifically balanced.</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>The program avoided commercial bias or influence.</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Overall, the program met my expectations.</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>I would recommend this program to my colleagues.</td>
<td>5</td>
<td>4</td>
</tr>
</tbody>
</table>

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.  

____________________________________________________________________________________________________________

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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:  

____________________________________________________________________________________________________________

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CE Activity Code: 07HC02- DE01
The southern New Jersey counties of Camden, Burlington, Gloucester and Salem are currently home to approximately 2,400 people with HIV/AIDS. The region is part of the Ryan White CARE Act Title I Philadelphia Eligible Metropolitan Area, and is therefore one of the 51 areas of the country with the highest HIV/AIDS impact and need.

In 1989, before the passage of the CARE Act, awareness of the HIV/AIDS epidemic and its impact on this corner of New Jersey was very low. One group of medical professionals in Voorhees believed that this was an epidemic that would soon be devastating to many hundreds of people in the area. They decided to pool their resources and their energy to create a healthcare training conference that would help answer the many questions about caring for HIV positive people and recruit more healthcare professionals to take an active role in the struggle against the virus.

According to Dr. David Condoluci, an infectious disease specialist and the leader of Garden State Infectious Disease Associates in Voorhees, “there were more questions than answers, few doctors knew about or wanted to take care of people living with HIV.” Dr. Condoluci, along with Karen Wallenobrien, MSW, and Judy Comito, RN, decided to take an active stance: they would educate primary care providers on the disease, first trying to reduce the fear that is created where knowledge is thin, then showing them how to work with their patients to help keep them alive and comfortable as long as possible. In those dark days of the HIV epidemic, there was little more that medicine could do. This was the genesis of the HIV Medical Update, the largest and longest running HIV/AIDS continuing medical education event in New Jersey.

The first conference took place at the Mansion in Voorhees in December of 1989. According to Dr. Condoluci, about 100 providers were in attendance. The focus at that time was on educating providers about the cause of AIDS. Treatment was limited to zidovudine (AZT) monotherapy. The prevention and treatment of opportunistic infections such as pneumocystis carinii pneumoniae (PCP), mycobacterium avium complex (MAC) and others was a vital learning objective for the conference, as these were the bullets fired by the guns of AIDS that most often took their patients lives.

Fast forward to the end of 2005: AIDS is now being talked about as a chronic, manageable condition, with 18 antiretroviral agents approved and more on the way. There is hope for a vaccine, and the federal and state government response to the crisis has created a safety net so that people with no health insurance can receive the same level of care that celebrities and middle class people who are infected enjoy. Yet, despite these unprecedented medical and political victories, HIV/AIDS remains a global pandemic, which is killing people in every country, and in this country remains challenged by stigma and ignorance.

From an educational perspective, the needs of the healthcare provider population change almost as quickly as the virus mutates. The science of HIV treatment is changing with incredible rapidity. It is difficult for most professional school curricula to do more than brush the surface of HIV/AIDS prevention and treatment. The fast tracking of new medications through clinical trials and FDA approval makes continuing education vital for all providers, no matter what their level or specialty. Because HIV is transmitted so silently and can cut across all boundaries of health, race, class, age, geography etc., every healthcare professional must be fluent in HIV basics, such as transmission, testing, stigma, and the ramifications of diagnosis.

The HIV Medical Update has served as an educational anchor for southern New Jersey’s healthcare provider population for most of the epidemic. The conference has grown to serve almost 300 providers each year. Although a day of training will not create experts from the general practice population, it does ensure that attendees are kept current on the state of the disease. It also serves as a link to other resources, such as the AIDS Education and Training Center, which provides one on one clinical training and consultation throughout the year.

Continued on next page.
The 2005 Update was a perfect example of how a traditional lecture style activity can serve as the platform to launch learning. In order to effectively treat people living with HIV, that education must continue throughout the year.

The 2005 HIV Medical Update was typical of the 15 that preceded it: tailored to southern New Jersey, yet providing a broad scope of the state of the epidemic.

John Bartlett, MD, of the Johns Hopkins University School of Medicine, headlined the agenda. Dr. Bartlett, one of the preeminent names in the field spoke on the future of HIV, and set the stage for the day. The fast paced agenda included talks on gynecological concerns for HIV positive women, an update on pediatric HIV, lipid and cardiovascular issues in HIV positive patients, caring for the incarcerated HIV positive patient, hepatitis co-infections, optimizing adherence, as well as an overview of the global impact of the epidemic, all neatly covered and referenced by a team of highly expert faculty that included many southern New Jersey clinicians.

Dr. Condoluci and his team at Garden State Infectious Disease Associates, continue to be dedicated to education and training for the southern New Jersey community of caregivers. Although their practice, a comprehensive multidisciplinary team of experienced healthcare professionals, is one of the busiest in the state, they include and prioritize a mission to share their expertise with the community. As the Southern New Jersey Local Performance Site of the New York/New Jersey AIDS Education and Training Center, their commitment to training continues throughout the year (see resource section for their contact information).

An outgrowth of the Update since 2004 has been the initiation by Dr. Condoluci of the Teddy DePrince award (see next page). This award is named after a young man, who with his mother Elaine, fought for the New Jersey Hemophilia Justice Act of 1996. Dr. Condoluci and his team identify an outstanding member of the southern New Jersey community and honor him or her at the faculty dinner the night preceding the conference.

This year’s conference is scheduled for December 8, 2006, and will take place at the Hilton at Cherry Hill. Watch this publication for further details, or visit the NY/NJ AIDS Education and Training Center website: www.nynjaetc.org.

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

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

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)

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

Hotlines

**NATIONAL HIV/AIDS CLINICIANS’ CONSULTATION CENTER**

[www.ucsf.edu/hivcnt](http://www.ucsf.edu/hivcnt)

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

National Perinatal HIV Consultation and Referral Service: 888-448-8765 (888-HIV-8765)
Amitabha Das, MD, the HIV/AIDS Coordinator for Burlington County, New Jersey, received the 2nd Teddy DePrince Award from Garden State Infectious Disease Associates and the University of Medicine and Dentistry of New Jersey’s Center for Continuing and Outreach Education, Division of AIDS Education.

This award is named after a young man, who, along with his mother Elaine, fought for the New Jersey Hemophilia Justice Act of 1996. Mrs. DePrince went on to write *Cry Bloody Murder: A Tale of Tainted Blood* in 1997, after losing two of her sons to HIV/AIDS. She was the first recipient of the award in 2004.

This year’s award recipient, Dr. Das, brings something unique to the HIV/AIDS field in the New Jersey: his expertise from overseas (specifically, Calcutta, now Kolkata, India). Dr. Das played a pioneering role in his native land, where he organized clinics for commercial sex workers in the mid 1990’s, as the AIDS epidemic was gathering momentum on the Indian subcontinent. He broke new ground in penetrating the class structure of Indian society to reach out to this neglected and medically underserved group of women with messages of safety and prevention of sexually transmitted diseases. His work in India prepared him for working with the stigma that serves to stifle the questions that uncover HIV transmission risk, as well as delay the identification of HIV diagnosis.

Dr. Das came to the Burlington County Health Department in 1997. His work as the HIV/AIDS Coordinator has allowed him to set up a network and a feedback loop between the HIV treatment centers in the area, hospitals, drug treatment centers and HIV/AIDS Service Organizations. He remains connected to all of the clients he counsels, even once they are in medical care. His presence is an additional support to HIV positive people as they begin the often-difficult steps of HIV care and treatment. For the many others who test negative, Dr. Das’ contact is a reminder of the need to change the behavior that brought them to the health department for a test. He is open and nonjudgmental in discussing sexual behavior and drug use with all his clients.

Dr. Das remains passionate about his work. He describes the challenges of educating people about HIV testing, including those who see testing as a means of prevention. He identifies 10-12 HIV positive people per year, but states that even more important is the work that he is able to do with everyone he encounters on changing their behavior to lessen the risk of HIV transmission.

**BURLINGTON COUNTY HEALTH DEPARTMENT:** 15 Pioneer Boulevard, Westampton, NJ, 609-265-5929

**NJ Rapid Testing Hotline:** 1 (866) HIV-CHECK
In the News!

SMART study halted

INTERNATIONAL HIV/AIDS TRIAL FINDS EXCESSIVE RISK IN EPISODIC THERAPY

The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), announced that enrollment into a large international HIV/AIDS clinical trial comparing continuous antiretroviral therapy with episodic drug treatment guided by levels of CD4+ cells has been stopped.

The SMART study, or Strategies for Management of Anti-Retroviral Therapy, was designed to determine which of two HIV treatment strategies would result in greater overall clinical benefit. HIV-positive volunteers were assigned at random to either a viral suppression strategy in which antiretroviral therapy (ART) was taken on an ongoing basis to suppress HIV viral load; or an episodic drug conservation strategy, in which ART was started only when the CD4+ cell level dropped below 250 cells/mm$^3$. Volunteers in the drug conservation group were taken off ART—with the aims of reducing drug side effects and preserving treatment options—whenever their CD4+ cells were above 350 cells/mm$^3$. A total of 5,472 participants in 318 clinical sites in 33 countries were enrolled in the study. (For more details see http://www.smart-trial.org).

The SMART Study Data and Safety Monitoring Board (DSMB), an independent committee composed of clinical research experts, statisticians, ethicists, and community representatives investigators, reviewed data in January and found that patients receiving episodic therapy, or drug conservation, had twice the risk of disease progression (the development of clinical AIDS or death). These patients also had an increase in major complications such as cardiovascular, kidney and liver diseases, often associated with ART. Researchers had hoped that the complications would be seen less frequently in patients receiving less antiretroviral medication. The DSMB recommended to investigators that they halt enrollment, and the SMART study did so on January 11, 2006. The SMART Executive Committee and NIAID reported their findings to site investigators and participants, and recommended that the drug conservation group resume antiretroviral therapy.

Excerpted from NIH press release (January 18, 2006) and “Questions and Answers” page on NIH website:


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FDA Alerts

CLASS 1 RECALL: ORTHO-Clinical Diagnostics VITROS® IMMUNODiAGNOSTIC HBsAg CONFIRMATORY KIT

Date Recall Initiated: December 15, 2005

Reason for Recall: An unknown component in the diluting solution used to test blood and serum samples may produce ‘Not Confirmed’ results for samples found to be positive with the initial test, which can cause some results to be classified as false negatives.

- FDA Comments: False negative results may prevent some patients infected with or carrying the hepatitis B virus from receiving necessary treatment. This is especially true for pregnant women whose tests show false negative results. When their fetuses are born, they will be presumed negative, and not treated with the HBIG (hepatitis B immunoglobulin) and hepatitis B vaccine. Such infants have a 90% chance of progressing to chronic hepatitis B virus infection resulting in possible liver transplantation or early death.

- Ortho-Clinical sent letters via overnight mail to medical facilities, testing labs and public health agencies on 12/15/2005, instructing customers to discontinue use and discard remaining inventory. In a separate Q&A sheet, the company recommends that previously reported results be reviewed.

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Excerpted from NIH press release (January 18, 2006) and “Questions and Answers” page on NIH website:

Introduction

In June 2001, the New Jersey Department of Health and Senior Services (NJDHSS) released its health objectives for 2010 in a document entitled Healthy New Jersey 2010: A Health Agenda for the First Decade of the New Millennium (HNJ2010). This set of state-specific objectives was developed as a companion document to the national effort, Healthy People 2010, and in continuation of New Jersey’s initial set of health objectives, Healthy New Jersey 2000: A Public Health Agenda for the 1990s. Two overall assessments of progress toward achieving the HNJ2000 objectives were published by NJDHSS during the decade of the 1990s, as well as a journal article on the final achievement of the HIV/AIDS objectives, published in 2004. New Jersey has made substantial progress toward reaching its HIV/AIDS objectives by 2010 in a number of areas, although there are still disparities in some groups.

HNJ2010 was designed for use as a means of monitoring and tracking health promotion and disease prevention objectives in the state. Programmatic information and measurable objectives were grouped into five major health areas for purposes of the two-volume document:

1. Overall Health Status;
2. Access to Health Care;
3. Fundamentals of Good Health;
4. Preventing and Reducing Major Diseases; and

Nine major disease categories are encompassed under the heading, Preventing and Reducing Major Diseases, including HIV/AIDS. Each of the nine diseases has a separate chapter, which includes a discussion of prevention and treatment potential, current program efforts throughout the state and statement of measurable objectives with specific targets and preferred 2010 endpoints.

According to data from the Centers for Disease Control and Prevention, New Jersey ranked ninth among the states in number of new cases of AIDS in 2003. Additionally, New Jersey ranked fifth in the number of cumulative AIDS cases among all the states. In New Jersey in 1990, HIV/AIDS was the fifth leading contributor to the years of potential life lost (YPLL). Gender and race/ethnicity are particularly important variables in assessing the burden of HIV/AIDS in the state. New Jersey has the highest proportion of women among cumulative AIDS cases and ranks third in cumulative reported pediatric AIDS cases. In addition, HIV disease ranked fourth among the leading causes of death in the state’s black population in 2000, while ranking only nineteenth in deaths in the white population. In a 1999 survey of New Jersey residents, HIV/AIDS was identified as the third leading health issue in the state. Among black New Jerseyans, HIV/AIDS was the health issue of greatest concern.
The year 2010 objectives for HIV/AIDS emphasize populations that have been particularly adversely impacted. This article will review progress that has been made in achieving 2010 objectives related to reducing incidence rates of HIV disease, and AIDS in age/race-ethnicity/gender specific populations of greatest interest and will present informed opinion on the factors responsible for improvement, or lack of progress, as well as judgment on what is needed to achieve these objectives by 2010.

**Methods**

There are four objectives in HNJ2010 that aim to reduce the incidence of HIV disease among subgroups of the population by 2010: one each for females aged 15 through 44 years; males aged 15 through 44 years; the population 50 years and above; and the population aged 13 through 24 years. The first two of these contain separate targets for all race/ethnicity groups for which there are adequate data. The objective intended to reduce the incidence of HIV infections among persons 50 and over encompasses separate targets for males and females in this age group, in addition to the total. The objective aimed at reducing HIV disease among adolescents/young adults aged 13 through 24 years does not have any targets for subpopulations. In addition to the four objectives that address the reduction of HIV disease incidence there is an additional objective aimed at reducing the incidence of AIDS among the state’s population, with individual targets set for each race/ethnicity group with sufficient cases for analysis.

The data to measure progress on achievement of all of these objectives were obtained from the HIV/AIDS reporting system (HARS). HARS has collected data on New Jersey residents with HIV/AIDS since 1993, after HIV infection (with or without AIDS) became a reportable condition in New Jersey. HARS incorporated data from the previously existing AIDS reporting system, which collected data on AIDS cases diagnosed from 1979 through 1992. An HIV case is a person diagnosed as infected with the HIV virus and reported to HARS. Incidence of AIDS is defined as the onset of new cases and is represented by the reporting of diagnosed cases of AIDS in HARS. An AIDS case diagnosed and reported to the system is considered an incident case for the year of diagnosis. A person previously diagnosed with HIV infection, (but not AIDS), in HARS whose disease progresses to AIDS status, is considered an incident AIDS case for the year in which the AIDS diagnosis is made.

A quantitative measure called a Progress Quotient was calculated for each measurable objective or sub-objective. This is the progress measure used by the National Center for Health Statistics in its updates, Healthy People 2000 Midcourse Review and 1995 Revisions and Healthy People 2000 Final Review. The Progress Quotient formula is:

\[
\frac{\text{most recent value} - \text{baseline value}}{\text{year 2010 target} - \text{baseline value}} \times 100
\]

The Progress Quotient divides the progress that has been made to date (the difference between the baseline and the most recent value) by the total progress expected (the difference between the baseline and the target) and multiplies the result by 100 to yield a percentage. The baseline for each of the incidence objectives in this report is for 1998, and the most recent value is for data year 2002. It is possible to have Progress Quotients of zero, (no change from the baseline), and negative Progress Quotients, (where the current value is worse than the baseline). The Progress Quotient can be used to make comparisons on progress toward achievement of objectives between objectives, and among the subpopulations for which targets have been set. One of the major weaknesses of the Progress Quotient is that it only measures the improvement between the baseline and the current value and does not provide any indication of the fluctuations between the baseline and the current value being measured.

One of the co-authors of this article, an MPH/MD student at the University of Medicine and Dentistry of New Jersey, as part of her field work project conducted interviews of the directors within each service unit of the Division of HIV/AIDS Services (DHAS) at NJDHSS to elicit informed opinions on which programmatic efforts were responsible for the progress that has been made as measured by the Progress Quotients and what is needed to reach each of the targets by 2010. She also conducted interviews of representatives from related government, non-profit and for-profit organizations, as well as an interview with a person living with HIV. Interview questions followed the following framework:

- What has worked in facilitating achievement of the Healthy New Jersey 2010 HIV/AIDS objectives?
- What has not worked in facilitating achievement of the Healthy New Jersey 2010 HIV/AIDS objectives?
- What is needed to facilitate progress?

**Results - Interviews of Program Staff and Other Interested Individuals**

What are the successes in reducing incidence of HIV disease and AIDS, and how has this progress been accomplished? Program staff identified the most successful outcomes of HIV prevention and care efforts.
• Decrease in the rate of perinatal transmission
• Targeted interventions for both prevention and treatment
• The transformation of prevention efforts to a behavior change model
• Control of occupational transmission
• Implementation of the AIDS Drug Distribution Program, which has had an open formulary including antiretroviral medications; the program is credited with having very liberal eligibility criteria, with ease of access via a pharmacy-based distribution system.

What have been the obstacles, shortcomings, and disappointments in reducing the incidence of HIV disease and AIDS? Program staff provided a wide variety of responses.
• Current prevention efforts focusing on high-risk behaviors do not change outcomes much; sex and drug addiction behaviors are difficult to influence.
• Risk behaviors have not been adequately addressed.
• The appropriate groups are not well-targeted with prevention messages, in particular, the adolescent, 50 and over population, immigrants, migrant workers, and other potentially high risk populations.
• The decentralization of HIV/AIDS efforts in New Jersey; the rapidity of response to the epidemic led to a “quilting together of existing systems instead of a unified response,” which still exists today.
• Lack of capacity building
• New Jersey is not taking advantage of the benefits of and need for widespread needle exchange programs.
• Lack of awareness in the general population
• Lack of effectiveness in addressing disparities
• More should be done to identify positives who do not know they are positive

What is needed to facilitate achievement of the Healthy New Jersey 2010 goals of reducing HIV incidence? Program staff recommended changes in funding, messages, emphasis on target groups, and organizational collaborations.
• More funding for prevention and diagnosis
• Need to address race- and gender-based disparities
• Expand rapid HIV testing
• More community level prevention; partnerships with the community and strengthening of community based organizations
• Targeted outreach with population-specific curricula
• Make HIV testing routine, with increased access to rapid testing
• Support for needle exchange and distribution
• An increase in evidence-based prevention messages
• Condoms should not be just available, but should be distributed
• Expanded contact elicitation following positive HIV test results
• Testing of minors
• Collaborations between nongovernmental organizations and government agencies, and between HIV/AIDS organizations and other groups addressing related problems such as mental health, disability, and corrections

Discussion

The Progress Quotient measures the percent of the targeted improvement that has been accomplished as of, in this case, 2002. The Progress Quotient is dependent on the degree of improvement that is expected over the decade and the amount of change that has taken place in the time between the baseline and the date of the most recent measurement. The targets for 2010 in this document were set to narrow the major gaps in incidence by race/ethnicity and gender, resulting in greater expected improvements in the higher incidence rates at baseline. Setting targets differently would result in different Progress Quotients, with any given level of change in the measure.

The incidence among both males and females aged 15 through 44 years declined sufficiently by 2002 to make substantial progress in reaching the respective targets, 49 percent in females in this age group and 66 percent in the comparable male rates. All of the race/ethnicity groups made substantial progress toward the targets, with the highest Progress Quotients evident in white non-Hispanic females and Hispanic males and females. It should be noted that the Hispanic targets were set for lower expected improvement than the other groups. Improvements targeted in the black non-Hispanic males and females were more drastic than in other groups. Improvements targeted in the black non-Hispanic males and females were more drastic than in other groups, therefore the Progress Quotients are a bit lower than those in the total populations.

The incidence rate of HIV disease in the fifty and over population actually increased between the baseline and 2002, which led to a negative Progress Quotient. The incidence rate in males in this age group improved slightly over the period while the female rate increased from 7.0 to 8.1 per 100,000 population, which caused a negative Progress Quotient. Because the number of female cases is relatively small, the incidence rate may fluctuate from year to year; so more years of data are needed to confirm this as the true incidence trend.

The incidence rate in adolescents/young adults improved slightly over the time period 1998 through 2002, although the number
of cases is small and the incidence rate varies widely from year to year.

The targets for AIDS incidence have shown considerable progress overall and in each of the race/ethnicity groups, having achieved almost 60 percent of the target by 2002. Although the Progress Quotient was slightly lower in the black non-Hispanic population, this target was set more ambitiously than the other groups’ targets, in an attempt to narrow the gap in rates.

The program staff of DHAS and other respondents found a number of positive program strategies that contributed to the overall improvement in incidence rates indicated by the data from 1998 through 2002. The decrease in the rate of perinatal transmission is one of the most dramatic successes in reducing cases of HIV infection among the young. The staff credits targeted interventions in prevention and the development and implementation of a behavioral change model for prevention efforts in reducing HIV disease incidence rates. The control of occupational transmission has also helped to prevent cases due to transmission to health care providers and other exposed workers. The AIDS Drug Distribution Program, with its liberal eligibility criteria and ease of access, is viewed as important in delaying the progress of HIV infection to AIDS and therefore resulted in an almost 60 percent accomplishment of the overall target in this area by 2002.

At the same time, difficulties are perceived in identifying and developing prevention interventions that can make major changes in sex and drug addiction behaviors. The data confirm the suggestion from interviewed stakeholders that some sections of the population are not well targeted with prevention messages, in particular the adolescent/young adult and over 50 populations. Although there has been slight narrowing of the gap in incidence rates by race/ethnicity, rates in minority populations remain unacceptably high. Some staff felt that New Jersey should make use of needle exchange programs and, in addition, that testing of high-risk persons needs to be expanded.

A number of different strategies were suggested to further improve the incidence rates of HIV disease in the state: more community partnerships and strengthening of community based organizations by building capacity, more targeted outreach for specific population groups, greater access to testing, expansion of rapid testing, support for needle exchange, distribution of condoms, the increased use of evidence-based prevention messages and collaborations between various organizations charged with dealing with problems related to HIV disease. Some of these strategies would require additional funding.

In 1995, recognizing the need to further target HIV prevention efforts by risk behavior and to strengthen the focus of those efforts on behavior change rather than information transfer, the NJDHSS restructured its community-based HIV prevention program portfolio. In 2000, the targeting of HIV prevention efforts toward people living with HIV (PLWH) as an effective means of reducing HIV transmission was added to that portfolio. In 2003, a number of rigorously evaluated, science-based HIV prevention interventions first became available from the Centers for Disease Control and Prevention (CDC) for use in strengthening targeted prevention efforts. Referred to as the Diffusion of Effective Behavioral Interventions (DEBI) curricula, in 2004 these new interventions were implemented at community-based HIV prevention programs in New Jersey. While DEBI curricula are available for many targeted populations, including PLWH, African American women, IDU, adolescents and men who have sex with men, they do not currently exist for all populations, including people over 50 years of age and Latina women among others. More research and development to expand the portfolio of DEBI curricula to additional at-risk populations are needed.

These incidence objectives should be updated again when additional years of data are available. The advent of rapid HIV testing in 2003 and the expansion of this test to counseling and testing sites, hospitals, emergency departments and mobile vans is expected to have a major impact on the number and rate of testing in all areas of the state and may have an effect on incidence rates of HIV infection. Implementation of some or all of the strategies suggested by program staff for this project might make a positive difference in incidence rates. It is critical to the course of trends in HIV/AIDS in the state to monitor the state’s progress on meeting the health objectives for HIV disease incidence.

References:

The incidence objectives in HNJ2010 and percentage accomplishment (Progress Quotients) included:

(1) Reduce the incidence of HIV disease among females aged 15 through 44 years per 100,000 population.

<table>
<thead>
<tr>
<th>Race/ethnicity</th>
<th>1998 Baseline</th>
<th>2010 Target</th>
<th>Value in 2002</th>
<th>Progress Quotient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>38.1</td>
<td>20.1</td>
<td>29.3</td>
<td>48.9%</td>
</tr>
<tr>
<td>White non-Hispanic</td>
<td>8.3</td>
<td>5.5</td>
<td>5.9</td>
<td>85.7%</td>
</tr>
<tr>
<td>Black non-Hispanic</td>
<td>176.3</td>
<td>49.9</td>
<td>131.4</td>
<td>35.5%</td>
</tr>
<tr>
<td>Hispanic</td>
<td>36.8</td>
<td>27.3</td>
<td>30.8</td>
<td>63.2%</td>
</tr>
</tbody>
</table>

(2) Reduce the incidence of HIV disease among males aged 15 through 44 years per 100,000 population.

<table>
<thead>
<tr>
<th>Race/ethnicity</th>
<th>1998 Baseline</th>
<th>2010 Target</th>
<th>Value in 2002</th>
<th>Progress Quotient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>64.6</td>
<td>45.7</td>
<td>52.1</td>
<td>66.1%</td>
</tr>
<tr>
<td>White non-Hispanic</td>
<td>23.6</td>
<td>13.7</td>
<td>20.3</td>
<td>33.3%</td>
</tr>
<tr>
<td>Black non-Hispanic</td>
<td>244.4</td>
<td>94.0</td>
<td>170.5</td>
<td>49.1%</td>
</tr>
<tr>
<td>Hispanic</td>
<td>88.5</td>
<td>77.8</td>
<td>69.7</td>
<td>175.7%</td>
</tr>
</tbody>
</table>

(3) Reduce the rate per 100,000 population of newly diagnosed HIV infections among persons at least 50 years of age.

<table>
<thead>
<tr>
<th>Population</th>
<th>1998 Baseline</th>
<th>2010 Target</th>
<th>Value in 2002</th>
<th>Progress Quotient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total 50+</td>
<td>13.6</td>
<td>7.8</td>
<td>13.8</td>
<td>-3.4%</td>
</tr>
<tr>
<td>Males 50+</td>
<td>22.1</td>
<td>13.3</td>
<td>20.9</td>
<td>13.6%</td>
</tr>
<tr>
<td>Females 50+</td>
<td>7.0</td>
<td>3.6</td>
<td>8.1</td>
<td>-32.4%</td>
</tr>
</tbody>
</table>

(4) Reduce the incidence of HIV disease among adolescents/young adults aged 13 through 24 per 100,000 population.

<table>
<thead>
<tr>
<th>Population</th>
<th>1998 Baseline</th>
<th>2010 Target</th>
<th>Value in 2002</th>
<th>Progress Quotient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total 13-24 Years</td>
<td>12.6</td>
<td>6.6</td>
<td>11.8</td>
<td>13.3%</td>
</tr>
</tbody>
</table>

(5) Reduce the incidence per 100,000 population of AIDS among New Jersey residents.

<table>
<thead>
<tr>
<th>Race/ethnicity</th>
<th>1998 Baseline</th>
<th>2010 Target</th>
<th>Value in 2002</th>
<th>Progress Quotient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>21.5</td>
<td>14.6</td>
<td>17.5</td>
<td>38.6%</td>
</tr>
<tr>
<td>White non-Hispanic</td>
<td>6.4</td>
<td>4.3</td>
<td>5.4</td>
<td>47.6%</td>
</tr>
<tr>
<td>Black non-Hispanic</td>
<td>100.8</td>
<td>31.1</td>
<td>75.2</td>
<td>36.7%</td>
</tr>
<tr>
<td>Hispanic</td>
<td>27.1</td>
<td>21.3</td>
<td>24.7</td>
<td>41.4%</td>
</tr>
</tbody>
</table>
HIV Counseling and Testing Sites:
HIV Rapid Test information, test site map
www.state.nj.us/health/aids/rapidtesting/index.shtml
NJDHSS-DHAS listing of all NJ HIV Counseling and Testing Sites:
www.state.nj.us/health/aids/ctsites.htm
HIV Rapid Testing hotline: 1 (866) HIV-CHECK
NJ AIDS/STD Hotline: 1 (800) 2377

Adolescent Medical Care
S.T.A.R.T. Program
(Screening, Treatment and Risk Reduction for Teens)
UMDNJ-Division of Adolescent and Young Adult Medicine
Newark, NJ
(800) 375-9482

Statewide Family Centered HIV Care Network (Ryan White Title IV)
Francois-Xavier Bagnoud Center at UMDNJ
Newark, NJ
(973) 972-0380
Newark Beth Israel Medical Center
Newark, NJ
(973) 926-8004

Jersey City Medical Center
Jersey City, NJ
(201) 946-6148
Robert Wood Johnson Medical School
New Brunswick, NJ
(732) 235-7894
Jersey Shore Medical Center
Neptune, NJ
(732) 776-4271

For more information on Adolescents and HIV, see cover article
INTERNET RESOURCES

**HIV/AIDS INFORMATION AND GUIDELINES**

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

www.state.nj.us/health/aids/aidspry.htm  
www.state.nj.us/health/aids/aidsqrtr.htm  
New Jersey rapid testing FAQs, locations, and articles:  
www.state.nj.us/health/aids/rapidtesting/index.shtml

US Dept. of Health & Human Services

www.aidsinfo.nih.gov  
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#WVWW  
Rapid Testing Web page:  
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/elists.htm

**HIV/AIDS TRAINING AND EDUCATION**

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

http://ccoe.umnj.edu/aids  
Training programs for HIV/AIDS health and social service professionals. You can register online for most UMDNJ HIV/AIDS continuing education courses at:  
www.peopleware.net/0646a  
Free online CME: Topics Include  
• Opportunistic Infections in HIV/AIDS  
• Rapid Diagnostic Testing for HIV  
• Impact of the New Guidelines for the Use of Antiretroviral Agents  
• Community Based HIV Treatment Adherence Support  
• Update on HIV and Hepatitis C Virus Co-Infection  
  
http://ccoe.umnj.edu/online/AIDSLine/index.htm

New York/ New Jersey  
AIDS Education and Training Center (AETC)

The NY/NJ AETC provides customized HIV/AIDS training for healthcare providers including clinical and allied health staff. The NY/NJ AETC website includes a regional training calendar, directory of community HIV resources, and clinician support tools and treatment references.  
www.nynjaetc.org

AETC National Resource Center

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

STD/HIV Prevention Training Centers (PTC)

Medical:  
Behavioral:  
www.urmc.rochester.edu/chbt

Addiction Technology Transfer Center (ATTC)

SAMHSA funded training, addiction treatment news  
Northeast ATTC:  
www.neatcc.org

Title X Family Planning Regional Training Center (RTC)

DHHS/OPA funded training:  
www.cicatelli.org/titlex/home.htm
SAVE THE DATES!

THURSDAY, APRIL 27, 2006, 1 - 3 PM

Satellite Broadcast:
Social Networks: A Recruitment Strategy for HIV Counseling, Testing, and Referral Services

The CDC and the Public Health Training Network will present a 2-hour satellite broadcast and Webcast on the rationale for the use of social networks as a recruitment strategy for HIV counseling, testing, and referral services. A panel of experts will present on components of the social networks strategy; assessing organization readiness for using the strategy; and available training and technical assistance; and answer viewer questions.

Where: viewing sites at NJN in Newark and Trenton.

For more information and to register: call Michelle Thompson: (973) 972-1293

TUESDAY, JUNE 6, 2006

HIV Clinical Update 2006:
The New Jersey Statewide Symposium

Where: Hilton at Woodbridge, Iselin, NJ

Join more than 200 clinicians and other HIV service providers in a one-day intensive update with leading HIV researchers and practitioners, including lectures and case-based workshops.

This conference is a collaboration of the UMDNJ - Center for Continuing and Outreach Education – Division of AIDS Education and the New Jersey Division of Health and Senior Services, Division of HIV/AIDS Services.

Keynote address:
Treating the Experienced Patient
Roy Gulick, MD, MPH [Weill Cornell Medical College]

Register online at www.peopleware.net/0646a
(800) 227-4852, option 3
Fee: $40.00 until 5/26/06, $50 on-site
Course Code: 06HC08

For program information, call Kimi Nakata: (973) 972-1246

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Please fax this page, including your mailing label and any changes, to (973) 972-3371.

☐ Please add me to the free subscription list. My contact information is below

☐ Please take me off the New Jersey AIDSLINE mailing list.

☐ My contact information has changed. I made the necessary corrections to my label below

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<th>Degree:</th>
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<tr>
<td>Day phone:</td>
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