



HIV Medical Alert

for primary health care providers
and health professionals

June 2001
Vol. 5, Issue No. 2

HIV Medical Alert provides clinicians with comprehensive and up-to-date information about diagnosis, treatment, and prevention of HIV.

HIV Medical Alert is published by Upper Hudson Primary Care Consortium, Glens Falls, N.Y., as part of the HIV Clinical Education Initiative. The Initiative is funded by the AIDS Institute of The New York State Department of Health (NYSDOH).
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HIV Medical Alert is also available online at www.upstate.edu/cei


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WELCOME to the *HIV Medical Alert* Newsletter Continuing Medical Education (CME) format. This activity has been planned and implemented in accordance with the Essentials and Standards of the Medical Society of the State of New York through the joint sponsorship of Glens Falls Hospital and Upper Hudson Primary Care Consortium. The Glens Falls Hospital is accredited by the Medical Society of the State of New York (MSSNY) to sponsor continuing medical education for physicians. The Glens Falls Hospital designates this continuing medical education activity for a maximum of 1 hour of Category I credit towards the American Medical Association Physician's Recognition Award (AMA-PRA). Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

Sexual Assault Post Exposure: Putting Policy into Action

by Lyn Stevens, MS, ACRN, NP

Introduction

The estimated risk of transmission of HIV for a single episode of penile/vaginal intercourse is estimated to be only 0.1%, and that for a single act of receptive anal intercourse 0.1% - 3.0%. However, the risk associated with rape may be much higher due to genital and rectal trauma and bleeding, exposure to multiple assailants, exposure through multiple receptive sites, and the presence of other sexually transmitted diseases (STD's).¹ After several instances of HIV transmission following rape were reported by clinicians in New York State, it became clear that survivors and practitioners would benefit from standardized post exposure prophylaxis (PEP) guidelines. In June 1998 the NYS DOH AIDS Institute published "HIV Prophylaxis Following Sexual Assault: Guidelines for Adults and Adolescents" which articulated the rationale for PEP and gave specific recommendations for treatment. This newsletter addresses those obstacles which communities and treating institutions must resolve to put this policy into action.

AIDS Institute Guidelines

Survivors of sexual assault should be considered candidates for HIV post-exposure prophylaxis (PEP) when significant exposure may have occurred, as defined by direct contact of the vagina, anus, or mouth with the semen or blood of the perpetrator, with or without physical injury, tissue damage, or presence of blood at the site of the assault. PEP should be initiated as soon as possible following exposure, ideally within one hour and generally not more than 36 hours post exposure.

Evaluation and Treatment

1. Obtain blood for baseline HIV serologic testing prior to beginning therapy. Refusal to undergo baseline testing should not preclude initiation of therapy. If pre-test counseling and/or HIV baseline testing is deemed burdensome in the urgent care setting, this can be deferred to the early continuing care setting.
2. Discuss with the survivor the potential benefits of prophylaxis, possibility of side effects, nature/duration of treatment and monitoring and importance of adherence should be discussed before initiation of therapy.
3. Prescribe the recommended PEP: **Zidovudine 300mg bid, Lamivudine 150mg bid and Nelfinavir 1250mg q12h for 4 weeks.**

4. Schedule a follow-up visit within 24 hours to review with the survivor the decision to accept PEP, to reinforce need for adherence to the regimen, and to arrange for follow-up care. If the survivor is initially too distraught to make a decision regarding treatment initiation, arrange for the patient to have a follow-up appointment within the 36 hour treatment window to reopen the discussion about PEP treatment.
5. Refer individuals placed on therapy to an HIV Specialist for follow-up management and monitoring of treatment.

Comprehensive guidelines are available through the regional HIV Clinical Education Coordinator or online at www.hivguidelines.org

Policy Design for Health Care Facilities

PEP following sexual assault is most frequently implemented in the Hospital Emergency Department. (ED). The most effective models of PEP have involved the planning and input of a variety of the hospital staff: medical director of the ED, nurse manager, social worker, pharmacist, and rape crisis staff in formulating the policy and procedure. The following elements are key features of an institutional PEP policy which are considered essential.

- **Application:** The above guidelines pertain to Sexual Assault not occupational exposure.
- **Triage:** If a patient meets the definition of sexual assault and presents within the 36 hour treatment window they should be triaged as Level 1.
- **Support Services:** A rape crisis counselor should be called to the ED and available when any sexual assault case is seen.
- **Examination:** Sexual Assault Nurse Examiners (SANE) nurses-specially trained forensic nurses equipped to conduct sexual assault exams-should be utilized wherever possible.
- **PEP:** If PEP is indicated, staff can then follow the treatment guidelines, provide antiretroviral therapy, patient teaching and medication information handouts.
- **HIV Testing:** In the PEP policy, designate the healthcare staff who will provide pre-test counseling and obtain informed consent. Indicate who will provide post-test counseling. For example, the emergency department can provide pre-test counseling and submit the baseline HIV test. The physician providing follow-up care could provide post-test counseling and give the results of HIV testing. Alternatively the entire testing could be performed by the follow-up physician in the first few days post assault.
- **Follow-up:** Determine the available resources in the community for follow-up care. Is there an HIV Specialist? Will ED providers need to refer patients to their primary care physician or the physician on call? Once the appropriate provider is identified, notify them of the referral. It is important to clearly indicate to the continuing care physician what part of the PEP protocol has been completed and what further issues need to be addressed (i.e. completion of a Hep B immunization series).

Provider and Community Education

Once a hospital or urgent care center has finalized this policy and procedure, education of physicians and the community is vital. The primary care physicians (PCP) in every community constitute the continuum of care and should understand the process (policy) which occurs within treating institutions, the subsequent referral process, their responsibilities to successfully administer an effective program of care and the resources available. Participating PCP's should know the contact information for the nearest HIV Specialist in the area for consultation.

Community education is critical to the success of these guidelines. The NYS DOH AIDS Institute (AI) has provided training to all rape crisis staff/volunteers. Rape crisis staff/volunteers refer rape victims to the ED if contacted initially and come to the ED when called to provide assistance to all rape victims regardless of eligibility for HIV PEP. The rape crisis staff/volunteer plays a pivotal role in helping the survivor more completely understand the potential benefits of treatment and its side effects, as well as the importance of treatment adherence. The AI has also provided education to law enforcement officers and emergency medical responders. These agencies are frequently the first responders to rape and sexual assault and their awareness of the availability of PEP and the need for early treatment within the 36-hour treatment window will help to assure the effective administration of PEP.

Meeting the Common Challenges of PEP

Timely Administration

Law enforcement, emergency medical responders, rape crisis volunteers, community physicians, emergency department staff and consumers all need to be aware that HIV PEP is available and that it needs to be initiated as soon as possible within the 36 hour window of opportunity. Education for all these agencies is vital to the timely administration of antiretroviral therapy.

Availability:

The cost of PEP regime is approximately \$1,200. With limited third party resources available in 2001, this cost and procurement of drug is the responsibility of the individual and the prescribing institution. By involving the social service department and administration in the beginning stages of policy design, drug availability will be assured when the patient arrives in the ED. If the patient has no resources for PEP, the treating institution or clinic has the responsibility to provide immediate access to PEP and ensure ongoing drug availability to complete a 4 week course. Reimbursement options available to organizations and individuals include Crime Victims Bureau emergency payment, pharmaceutical companies compassionate need programs, and medicaid application. None of these are immediate sources of drug payment, however. The following figure summarizes payment options.

Payment Options for PEP

Medicaid	PEP is covered. Patient must meet the eligibility requirements for Medicaid. Recommendation: Order 1-2 weeks at a time to encourage follow-up visits.
Private Insurance (Little or no co-pay)	Encourage patient to use insurance. Recommend: Order 1-2 weeks at a time to encourage follow-up visits.
Private Insurance (Large co-pay or pay up-front)	<ol style="list-style-type: none"> 1. Order smaller amounts, perhaps 1-week supplies. 2. Ask family to help with the co-pay or the amount required. 3. Contact Crime Victims Board (CVB) for possible available funds. Patient must be over 18 to sign the application or ask parent to sign application. 4. Explore the use of compassionate use funds from pharmaceutical companies. 5. Contact your human service/social work department for special funds.
No Insurance (Patient cannot be forced to apply for Medicaid or CVB funds.)	<ol style="list-style-type: none"> 1. Treating institution provides immediate access to drugs. 2. Begin application process for Medicaid, if appropriate. (Coverage is not guaranteed.) 3. Contact Crime Victims Board (CVB) for possible available funds. Patient must be over 18 to sign the application or ask parent to sign application. 4. Explore the use of compassionate use funds from pharmaceutical companies. 5. Contact your human service/social work department for special funds. 6. May try compassionate use funds from pharmaceutical companies.
Chooses Not to Use Insurance	<ol style="list-style-type: none"> 1. Treating institution provides immediate access to drugs. 2. If patient is over 18, or parent will sign application, CVB Funds may be available. 3. Explore the use of compassionate use funds from Pharmaceutical companies. 4. Contact your human service/social work department for special funds. 5. May try compassionate use funds from pharmaceutical companies.

1. Crime Victims Board: The Crime Victims Board has a “General Emergency Award Procedure” designed to have a check available to the pharmacy in 3-4 days. It is important that the forms be filled out correctly and submitted with the supporting information requested. The award can only be \$500 but this can be done 3 times for a total of \$1,500. It is best if you know the Crime Victim Advocate in your community and work with them to pursue this process: they know the paper work, the community connections, and the procedure to expedite this process.

2. Pharmaceutical Companies: Pharmaceutical Companies have compassionate need programs. Each company works this process differently and each has different eligibility criteria. The most effective methods suggest that PEP policymakers call each company, obtain the proper paper work so that staff are pre-

pared if a client needs to access these programs.

- SmithKlineGlaxo Patient Assistance Program: AZT, 3TC, or Combivir. 1-800-722-9294
- Agouron Pharmaceuticals Viracept Assistance Program: Nelfinavir. 1-888-777-6637

HIV Testing

Many emergency rooms feel they are not equipped to deal with HIV pre-test counseling and obtaining informed consent. While baseline testing in this environment is suggested, other options exist. Baseline blood can be saved and subsequently submitted when consent by the patient has been given in the follow-up care. Alternatively, the entire process can be deferred for a few days to the follow-up provider. The figure below weighs the issues regarding timing of baseline HIV testing.

HIV Testing in the Emergency Department

Advantages to HIV Testing in the ED	Objections to HIV Testing in the ED
1. A core group of people is available to conduct the pre-test counseling and will become confident and efficient with the process	1. The test is not immediately available and the timing of the process does not change the initial management of the patient.
2. The patient is available and referral to another location for lab work is not necessary, diminishing the risk of a missed opportunity for testing.	2. Pre-test counseling is time consuming
3. The patient will have test results more quickly.	3. Test is performed too infrequently for staff to gain competence and pre-test counseling skill.
4. The PEP policy can effectively address post-test counseling by designating what department/office will complete this element and receive the HIV test result.	4. Staff is unable to provide the required post-test counseling.

Adherence to PEP

Approximately 77% of health care workers receiving PEP for occupational exposure experienced side effects, and only 40% completed therapy. Health care workers in these circumstances understand medications, have their medications paid for and have peer support, yet for one reason or another fail to adhere to this regime. In a New York State community hospital during 2000, of the 30 patients placed on PEP following sexual assault only 9 (30%) completed therapy. Medication adherence is an important issue and providers must discuss the medications with patients and provide information about:

- ~ possible side effects
- ~ specific strategies to diminish these symptoms
- ~ speaking to a provider first before stopping medication
- ~ where to call to discuss problems or questions regarding the regimen
- ~ medication fact sheets that are language appropriate and understandable
- ~ the importance of keeping frequent clinic appointments to review compliance and adverse effects

Maintaining provider/staff competence in appropriate PEP following sexual assault

The HIV prophylaxis training programs offered to post-rape treatment teams by the AI are designed to adequately prepare clinicians to aptly apply the PEP guidelines defined by New York State. This is available through the HIV Clinical Education Initiative which can be located at www.upstate.edu/cei and click on the CEI brochure. At the conclusion of this specific training, the learner should be able to:

1. Describe the structure of the advisory panel's protocols.
2. Explain the science behind PEP.
3. Identify the limitations regarding PEP efficacy.
4. Determine the risks and modes of HIV transmission.
5. Discuss the psychological burdens on the survivor and convey that understanding in pre- and post-test HIV counseling and testing.
6. Characterize the risks and benefits of HIV medications.
7. Cite the legal issues behind HIV testing of the assailant.

8. Discuss symptom management of the medication's potential side effects.
9. Name agencies for survivor referral use and follow-up medical care and counseling.²

Tool for Policymakers

A "QA Sexual Assault Post-Exposure Prophylaxis" checklist is provided below for CQI/Performance Improvement Committees to review the PEP policy for completeness and conformity to the NYS guidelines.

Q. A. Sexual Assault Post-Exposure Prophylaxis

1. Health Care Facility _____
2. Medical resources available:

<input type="checkbox"/> HIV Counselors	<input type="checkbox"/> SANE Program	<input type="checkbox"/> Rape Crisis Relationship
<input type="checkbox"/> PEP-aware Providers	<input type="checkbox"/> Drugs for Regimen	<input type="checkbox"/> Lab services
<input type="checkbox"/> Privacy	<input type="checkbox"/> Consent forms	<input type="checkbox"/> HIV Provider for referral
<input type="checkbox"/> Other: _____		
3. Policy/procedure provides for:
 - PEP for significant expo.
 - Treatment within 1 – 36 hours post-exposure
 - Assessment of survivor's ability to complete the regimen
 - Involvement of rape crisis counselor during HIV PEP discussion with survivor
 - Follow-up visit within 24 hours to review PEP decision
 - Arrangement of follow-up care if survivor initiates treatment
 - Consultation with HIV specialist
 - Discontinuance of therapy if perpetrator is HIV-
 - Baseline HIV testing of the survivor
 - Serologic HIV testing at 4 weeks, 12 weeks, 6 months and 1 year post-exposure
 - PEP Regimen using preferred/alternate drugs for a 4 week duration.
 - Barriers to financing the regimen have been effectively addressed using this plan: _____
 - Access to full regimen of medications is confirmed
 - Follow-up care for patients on PEP for treatment monitoring, HIV testing & specialist care
 - Adherence counseling
 - Patient education about s/s of primary HIV infection and subsequent need for immediate care
 - Referral process/consult with an HIV specialist
 - Discussion of the follow-up care plan with rape crisis counselor, SANE staff or outreach worker
 - Screening and treating for HBV and STDs according to NYSDOH protocol for the management of sexual assault survivors.

Reviewer: _____ Date of Review: _____

Resources

- Non-occupational HIV PEP Registry, 877-448-1737, or www.HIVpepregistry.org
- Rape Crisis Centers
- Crime Victims Bureau
- NYS DOH AIDS Institute – Guidelines "PEP Following Sexual Assault" www.hivguidelines.org
- HIV Counseling and Testing courses
- Clinicians Guide to the Management of HIV PEP Following Occupational Exposure. #0284 (Pocket-sized, laminated tri-fold.)
- CEI Line

References

1. HIV Prophylaxis following Sexual Assault: Guidelines for Adults and Adolescents, NYS DOH AIDS Institute, #9315, 6/98
2. HIV – Prophylaxis Following Sexual Assault: Recommendations for the State of California, Prepared by: Urban Community Health of the San Francisco Department of Health and the California HIV PEP after Sexual Assault Task Force in conjunction with The California State Office of AIDS, www.speakout.org.za/medical/rape/hiv_proph.htm

Author

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Continuing Education Test

HIV Medical Alert June 2001 Vol. 5 Issue No. 2

Continuing Education Post-test Note: This CME activity and quiz is designated for 1 credit.

Select the best answer for each of the following by placing an X in one box for each question or enter the requested information.

To earn credit:

1. Read the CME article.
2. Review the objectives
3. Study and apply the content to the objectives and to your practice.
4. Complete the Post-Test.

Objectives:

1. Understand the New York State guidelines for Post-Exposure Prophylaxis Following Sexual Assault.
2. State the risk of HIV transmission following sexual assault.
3. Determine the common challenges associated with PEP following Sexual Assault.
4. Identify the essential steps for establishing policy and procedure for PEP following Sexual Assault.

Post-test

1. PEP following sexual assault is recommended when:

- a. Survivor presents to ED within 36 hours of assault.
- b. Survivor is seen in your private office two weeks after assault.
- c. There has been direct contact of the vagina, anus or mouth with blood or semen of perpetrator.
- d. A and C

2. The recommended antiretroviral regimen for post-exposure prophylaxis is:

- a. D4T 40 mg. bid, 3TC 150mg bid and Nelfinavir 750mg tid
- b. AZT 300 mg bid, 3TC 150 mg bid and Nelfinavir 1250mg bid
- c. D4T 40 mb bid, ddI 200 mb bid and Nevirapine 200mg bid
- d. AZT 300 mg bid, 3TC 150 mg bid and Indinavir 800 mg q8h

3. Which health care professionals are vital to seamless implementation of this protocol:

- a. Emergency Department physicians, nurses and social workers.
- b. Rape Crisis Counselors.
- c. Law enforcement officials, Emergency medical responders.
- d. All of the above.

4. Providing comprehensive care for a survivor of sexual assault is necessary.

List the county you practice in: _____

Where is the nearest SANE program? _____

5. When starting a patient on antiretroviral therapy you should:

- a. Discuss side effects and side effects management.
- b. Advise patient to stop medications if not feeling well and call provider.
- c. Explain the importance of taking medication on time and not missing any doses.
- d. A and C

Evaluation of CME Activity HIV Medical Alert Vol. 5, No. 1

	Excellent	Good	Fair	Need s Improvement
Overall Activity				
1. Was the subject matter well balanced in fact & theory?	1	2	3	4
2. Was the format clear and easy to read?	1	2	3	4
3. Did subject matter have sufficient detail?	1	2	3	4
4. Was subject matter valuable for practical application?	1	2	3	4
5. Were objectives met?	1	2	3	4
6. Was the writer clear in content, sequence and style?	1	2	3	4
7. Overall program was? _____				

Comments/Topic Suggestions:

PLEASE PRINT CLEARLY TO ASSURE ACCURATE DOCUMENTATION OF CME CREDIT

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