NONOCCUPATIONAL

HUMAN IMMUNODEFICIENCY VIRUS

POSTEXPOSURE PROPHYLAXIS

GUIDELINES FOR

RHODE ISLAND

HEALTHCARE PRACTITIONERS

Nonoccupational HIV PEP Task Force
Brown University AIDS Program
and the Rhode Island Department of Health

Nonoccupational Human Immunodeficiency Virus Postexposure Prophylaxis Guidelines for Rhode Island Healthcare Practitioners

is a cooperative publication of the
Nonoccupational HIV PEP Task Force of the Brown University AIDS Program (BRUNAP) and the Rhode Island Department of Health (HEALTH)

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BRUNAP Nonoccupational AIDS Task Force and HEALTH gratefully acknowledge the invaluable assistance of Barbara Merchant, Brett Miller and Dennis Thomas in the creation of these guidelines.

 These guidelines were publicly released on August 1, 2002.

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RHODE ISLAND NONOCCUPATIONAL HIV PEP BACKGROUND

During 1982 to 2001, 2082 people in Rhode Island were diagnosed with AIDS, but probably even more became infected with HIV (1). In 2001 alone, 147 new HIV cases were diagnosed in Rhode Island (2). HIV postexposure prophylaxis (HIV PEP) is a secondary preventive method that may reduce the incidence of these infections.

HIV PEP is roughly divided into two types: occupational and nonoccupational. Occupational HIV PEP is a commonly accepted means of secondary HIV prevention for healthcare personnel. In 1988 Meylan et al. submitted the first published account of HIV PEP usage in which they described a laboratory technician in Switzerland who suffered a needlestick injury from an HIV-infected source (3). She received a four-day course of high-dose zidovudine and did not seroconvert. National guidelines from the Centers for Disease Control and Prevention (CDC) (in effect since 1996, and revised in 1998 and 2001) help guide occupational HIV PEP provision in the United States (4). The purported efficacy of occupational HIV PEP is based upon a multinational case-control study that observed an 81% reduction in the odds risk of infection for healthcare personnel who took zidovudine (AZT/ZDV) after needlestick injuries (5).

Nonoccupational HIV PEP (HIV NPEP) is typically employed after sexual assault, consensual sex, and needlestick injuries to at-risk patients who are not healthcare personnel. (The term "nonoccupational" may be misleading in some circumstances since it is intended to refer to exposures that do not occur in the healthcare setting. For example, a possible HIV exposure may occur in the performance of a job, e.g., a restaurant worker that sustains a needlestick from an injecting drug needle left in the trash, but still be termed "nonoccupational.") The efficacy of HIV NPEP is suggested by studies of occupational HIV PEP, perinatal HIV prophylaxis, and laboratory animals given HIV prophylaxis (6,7). Worldwide reports of HIV NPEP demonstrate that its use is increasing (8-13).

After noting several anecdotal reports of HIV infection following sexual assault, the New York State Department of Health AIDS Institute members created the first state guidelines for implementing HIV PEP after sexual assault (14). The California HIV PEP After Sexual Assault Task Force recently adopted state recommendations regarding HIV PEP following sexual assault. (15).

Since 1998 Australia and six European countries each have adopted HIV NPEP guidelines (16,17). The United States currently does not have national guidelines for HIV NPEP. In 1998, the CDC reviewed the subject of HIV NPEP, but did not issue formal guidelines governing its use (18).

The extent and appropriateness of HIV NPEP utilization in Rhode Island is not known. Based upon reports from community agencies, the Brown AIDS Program (BRUNAP) and the Rhode Island Department of Health (HEALTH) have recently become concerned that HIV NPEP provision in Rhode Island is not optimal and needs improvement. It is possible that at-risk people in Rhode Island have not received HIV NPEP because of a lack of formal guidelines on HIV NPEP and insufficient healthcare practitioner knowledge of HIV NPEP. As a result, some patients may have become HIV infected.

To address the need for formal guidance on HIV NPEP provision, BRUNAP joined forces with HEALTH and Rhode Island healthcare providers, health delivery groups and private and public service organizations to develop a comprehensive set of guidelines for the state. The purpose of this document is to help educate the Rhode Island healthcare provider community by providing a normative blueprint on managing persons possibly exposed to HIV outside the healthcare ("occupational") setting (as defined by the CDC). BRUNAP and HEALTH expect that these guidelines will influence clinical practice; practice protocols in emergency departments, clinics and other institutions; physician and patient expectations; and third-party payment decisions. It is hoped that the Rhode Island HIV NPEP guidelines can provide the basis for continuing medical education and to encourage further development of a consensus on clinical practice in this area.

NONOCCUPATIONAL HIV PEP KEY POINTS

HIV NPEP in context

- **HIV NPEP appropriateness**: The **majority** of blood and body fluid exposures do **NOT** require HIV NPEP provision. An evaluation for HIV NPEP is usually warranted, but its provision is not always necessary.
- **HIV NPEP ancillary concerns**: HIV NPEP is best provided as part of an HIV risk-reduction program. Referrals to or inclusions in such programs will be helpful in reducing further exposure to HIV. Social factors (e.g., risky sexual behavior, domestic/spousal abuse, sexual assault issues, drug abuse) are a frequent component of HIV exposures and need to be addressed when providing HIV NPEP.
- **HIV NPEP efficacy**: HIV NPEP efficacy is presumed from various sources and studies, but is not a proven means of HIV prevention. HIV NPEP is not yet endorsed, nor is it discouraged, by the CDC, and use of HIV medications for HIV NPEP is not an approved indication of the U.S. Food and Drug Administration.
- **Medication choice**: The medications listed in these guidelines are based upon recommendations from other sources' experience in multiple settings. Other regimens are possible and may or may not be more effective. Nevirapine, however, is NOT recommended for HIV NPEP.

Treatment timing

- **Initiation**: Administer the first dose of HIV NPEP without delay--preferably within one hour of exposure.
- **Treatment window**: Treat within 72 hours of an exposure. HIV NPEP following this period may not be effective, but it may be given in exceptional circumstances.
- **Duration**: Provide 28 days of uninterrupted therapy.
- **Exposure uncertainties**: Provide the highest level of HIV NPEP when the available information is unclear. Adjust later as necessary. HIV testing of the source of infection should NOT delay HIV NPEP provision.
- **Consultation**: Consultations should be sought as required, but should not delay the first dose of HIV NPEP. Medication adjustments, when needed, can be made following consultations.

Patient consent

- **Voluntary**: HIV NPEP should only be provided to patients capable of giving consent (or with the consent of a caretaker/parent/guardian) and who are willing and able to continue treatment for the full period. Some institutions may mandate informed consent.
- **Disclosure**: Patients must be informed that HIV NPEP (a) is not a cure for HIV infections; (b) is of unknown efficacy; (c) cannot be used as prophylaxis prior to risky sexual encounters or injecting drug use; and (d) must be taken under the care of a healthcare provider knowledgeable regarding HIV NPEP and in the context of an HIV/STDs risk reduction program (if applicable).
- **Decline of HIV NPEP**: Because the traumatic recent experience may adversely affect their capacity to accept HIV NPEP, patients who decline HIV NPEP should be reevaluated within 24 hours and offered or recommended to take HIV NPEP when it is indicated.

Testing

- **HIV NPEP baseline testing**: Patients receiving HIV NPEP should undergo baseline laboratory testing at the time of receiving their first dose or at least within 72 hours of receiving HIV NPEP. Testing should include HIV, hepatitis B and C, chemistry panel, and complete blood count testing for all patients, liver enzymes testing for those receiving protease inhibitors, and pregnancy testing for females of childbearing age. Other tests may be performed as indicated. Testing must not delay receipt of HIV NPEP. Patients who decline baseline testing should not be refused HIV NPEP.
- **HIV source testing**: Testing of the source should occur whenever possible. HIV NPEP provision should not be delayed to accommodate source testing.

GENERAL RECOMMENDATIONS FOR NONOCCUPATIONAL HIV PEP

Treatment Setting

Sexual assault survivors are best evaluated in an emergency department or equivalent healthcare setting where appropriate medical and social resources are available, and where emergency prophylaxis of all types can be immediately administered, when indicated. Patients evaluated for HIV NPEP following other exposures may be evaluated in any healthcare setting where appropriate medical and social resources can be consulted, and where emergency prophylaxis of all types can be readily administered.

HIV NPEP Priorities

Life-threatening medical conditions should be addressed first. If none exist, the patient's need for HIV NPEP should be immediately assessed and then HIV NPEP given quickly, when warranted. Further medical evaluation can proceed after this issue is resolved. Likewise, sexual assault survivors should seek and receive medical attention first, when possible, prior to any police or advocacy intervention.

HIV NPEP Timing

Healthcare providers should attempt to administer the first dose of HIV NPEP within one hour of the possible HIV exposure, or at least within one hour of presentation for medical care. HIV NPEP may be ineffective if initiated 72 hours or more after an HIV exposure. Healthcare providers should make every effort to treat within this 72-hour window. Initiating treatment beyond this period may be considered in exceptional circumstances.

Candidates for Receiving HIV NPEP

An HIV NPEP recipient must be willing, able, and prepared to take HIV NPEP for the entire treatment period; they must demonstrate (personally or via a caretaker/guardian/parent) an understanding of the medications administered, their risks, presumed but unknown efficacy, and side effects; and they must commit to continued care with a healthcare provider experienced with managing HIV NPEP.

Source's HIV Status

Although a majority of people potentially exposed to HIV know their source, most do not know the source's HIV status. The need for HIV NPEP should be investigated regardless of the source's HIV status. Suppositions regarding a source's HIV status especially in the absence of interviewing the source are likely to be inaccurate and may mislead the provider. Decisions to initiate HIV NPEP should then be based not only upon the source's status, but also the exposure type. A source may be known to be HIV uninfected, known to be HIV infected, or be of unknown HIV status.

Source HIV Testing

HIV testing of a human source of unknown HIV status should occur as soon as possible following the exposure. HIV NPEP may be discontinued if the source is HIV uninfected. Testing should not prolong or displace the consideration or provision of HIV NPEP. HIV testing of the injecting paraphernalia is NOT recommended because of the likely low yield of such testing and the unnecessary risk of injury to the test performers (4).

Initial Treatments

Vaginal or anal douching is NOT recommended after sexual exposures since it may increase the transmission of HIV and other sexually transmitted diseases (STDs). All needlestick and sharp injuries should be cleansed and treated, as necessary, using standard wound treatment techniques (4). No special precautions or techniques (besides continued universal precautions by the healthcare provider) are known to be indicated. Eyes splashed with blood and body fluids should be irrigated with at least one liter of normal saline (20). Contact lenses must be removed and discarded. Contaminated clothing should be promptly removed.

Other Emergency Prophylaxis

Anyone sustaining a blood or body fluid exposure who has not been previously vaccinated should be vaccinated against hepatitis B (4,21). Hepatitis B immunoglobulin may be considered for those who have not be previously vaccinated and sustain needlestick injuries. The CDC does not currently recommend hepatitis B immunoglobulin prophylaxis after sexual exposures. Tetanus vaccination (and immunoglobulin for those not previously vaccinated) should also be administered when indicated for lacerations, abrasions, and other wounds from sources that could potentially transmit tetanus (e.g. contaminated needles found in waste or soil).

Patients with sexual exposures should be offered prophylaxis against STDs other than HIV in accordance with current CDC recommendations. Recommended STD prophylaxis currently includes ceftriaxone 125 mg IM + azithromycin 1 g po + metronidazole 2 g po (or ciprofloxacin 500 mg po or ofloxacin 400 mg po instead of ceftriaxone, and doxycycline 100 mg po BID x 14 days instead of azithromycin) (21).

All females of childbearing age should also be offered pregnancy prophylaxis (21). Of the number of oral emergency contraception options, the most common regimen is norgestrel/ethinyl estradiol (Ovral) two pills initially, then two pills 12 hours later. Given the large pill burden of the emergency prophylactic regimens and their potential for inducing nausea, an anti-emetic (e.g., metoclopramide 10 mg) prior to prophylaxis should be given. The anti-emetic should not delay HIV NPEP provision, however. Intrauterine devices and current injectable regimens are not recommended emergency contraception methods.

Laboratory Testing

An HIV test and hepatitis B and C testing should be performed at baseline or at least within 72 hours of the exposure. HIV testing should comply with the current applicable guidelines. Baseline labs for HIV NPEP monitoring may also be drawn with these tests. These tests include a complete blood count, chemistry panel and liver-associated enzymes (if protease inhibitors are taken). It is preferable that these tests be obtained upon the patient's initial baseline evaluation; however, testing need not occur prior to and must not delay medication provision. Patient refusal to undergo testing is not a reason to withhold treatment per se; instead, patients should be strongly encouraged to be tested and their reasons for refusal should be addressed.

All females of childbearing age should undergo pregnancy testing unless they are currently pregnant, postmenopausal, or physically incapable of pregnancy (i.e., post-hysterectomy). Current use of oral contraceptives is not a contraindication to testing. Adolescent and adults who have had sexual exposures should undergo testing for gonorrhea, chlamydia (oral, anal, vaginal, cervical--as indicated), trichomoniasis, and syphilis in most circumstances, regardless if prophylaxis against STDs is prescribed.

Notification of Groups Who May Benefit from HIV NPEP

Selected populations, such as uninfected partners of an HIV serodiscordant relationship, should be apprised of the option of HIV NPEP by their healthcare practitioners, and arrangements made for quick access to medications when necessary. Certain groups may be at higher risk of suffering a needlestick or sharp injury, and should be told that HIV NPEP may be an option for them. These groups include non-healthcare personnel who are caretakers and family members of HIV-infected persons, sanitation workers, housekeeping and commercial cleaning workers, and other employees whose work might involve contact with disposed blood and body fluid contaminated sharp objects.

Repeated Requests for HIV NPEP and Continued HIV Risk-Taking Behavior

In general, repeated requests for HIV NPEP reflects a failure of primary HIV prevention. Enhanced attempts to eliminate the risk-taking behaviors should be employed rather than providing repeated rounds of HIV NPEP. There may be indications for repeated HIV NPEP, but chronic or continuous HIV NPEP should not be provided. HIV NPEP is best prescribed and more likely to be successful after discrete episodes and when coupled with risk reduction programs. The clinician should evaluate each patient's situation individually, but must be aware that HIV NPEP is not a substitute for allowing patients to continue to engage in HIV risk-taking activities, such as having unprotected intercourse with possibly HIV infected persons or sharing needles.

NONOCCUPATIONAL HIV PEP OVERVIEW

HIV NPEP is presented in these guidelines as a hierarchy of recommendations to help direct when HIV NPEP may be recommended, offered, or considered after a possible HIV exposure. In brief, HIV NPEP should be **RECOMMENDED** after an exposure to a known HIV-infected source, may be **OFFERED** after high-risk exposures, and may be **CONSIDERED** after low-risk exposures. Healthcare providers are not obligated to provide HIV NPEP after a given exposure, but should make potential recipients aware when these guidelines apply to their exposure. If HIV NPEP is **RECOMMENDED** for an exposure, it should be given to a patient unless other reasons or contraindications exist. If HIV NPEP should be **OFFERED**, then the healthcare provider should offer it to patients in context of a full discussion of the risks/benefits of this type of therapy and its applicability to them. If HIV NPEP should be **CONSIDERED**, then the provider should determine if HIV NPEP is applicable after the exposure then discuss its merits/demerits with the patient as appropriate. Under some clinical or other circumstances, a healthcare provider may offer or consider HIV NPEP for an exposure, but may appropriately inform the patient that HIV NPEP is not indicated or advisable for this exposure.

Step 1: Determine if the exposure meets criteria for an HIV NPEP evaluation		
HIV NPEP may be indicated for: • Unprotected vaginal or anal intercourse with persons at risk or known to be infected with HIV • Blood/body fluids exposures to injured/damaged (non-intact) skin or mucosae from sources that are HIV infected or at risk of HIV infection • Needlestick and sharp injuries from sources that are HIV infected or at risk of HIV infection • Oral sex involving exposure to seminal or vaginal secretions from sources that are HIV infected or at risk of HIV infection • Sharing of injecting drug paraphernalia with people who are HIV infected or at risk of HIV infection, and usage of shared drug paraphernalia with visible blood.	HIV NPEP is **UNNECESSARY** for: • Anyone who is HIV infected or has AIDS • Protected anal, oral, or vaginal intercourse without condom failure • Any blood/body fluid exposures to intact skin • Needlestick and sharp injuries from sources that CANNOT be HIV infected, e.g. sterile needles • Any body fluid exposures from saliva, urine, vomit, feces, or sputum unless visibly bloody • After any kissing or touching of another person, or after eating food or sharing utensils used by others • Any non-human bites/stings • Any human bites or scratches without blood exposure (unless severe and from a known HIV-infected person) • Discarded needles or sharps that have NOT been in contact with an HIV infected source or at-risk of HIV infection source	HIV NPEP should **NOT** be given: • As a substitute for primary prevention against HIV • As a prophylactic measure for those who wish to engage in practices that may expose them to HIV • As a prophylactic measure for women who wish to conceive from HIV-infected men • To any person who cannot (themselves or via a caretaker) commit to HIV NPEP

Step Two: Determine HIV serostatus or risk factors of source(s) (when known)

• Known non-HIV-infected source (e.g., sterile needle)
• Unknown HIV risk source (e.g., unknown sexual assailant or partner, discarded needle)
  • Sources at higher risk for HIV infection*
  • Sources at lower risk for HIV infection†
• Known HIV-infected source

**Sources at a higher risk for HIV infection include those who have multiple sexual partners, a sexually transmitted disease, or who engage in male-male sex, injecting drug use, prostitution or trading of sex for money or drugs, or have sex with known or suspected HIV infected persons (1,19). Objects with higher risk factors for HIV include use of the object for injecting drug use, medical use, embalming, or in sexual acts involving contact of the object with blood, vaginal fluids, semen or other potentially HIV-infected body fluids by human sources with higher risk for HIV infection; and retrieval of a discarded object from a geographic area, locale, venue or situation where injecting drug use is prevalent or where HIV prevalence is high.*

†*Source is not known to be at a higher risk for HIV infection*

Step Three: Based upon the exposure and source's HIV status, determine if HIV NPEP should be recommended, offered, or considered, and select an appropriate HIV NPEP regimen	
Exposure	**Course of Action**
Exposure to **KNOWN** HIV-infected source(s)	**RECOMMEND HIV NPEP** A. Source's **medication history** is **UNKNOWN** or the source is known **NOT** to be on anti-HIV medications zidovudine (AZT/ZDV) or stavudine (d4T) + lamivudine (3TC/Epivir) AND nelfinavir (Viracept) OR indinavir (Crixivan) B. Source's **medication history** is **KNOWN**: Under the advisement of a specialist knowledgeable in HIV NPEP and HIV medications, choose a medication regimen that takes into account the source's medication history and drug resistance. If this advice and information is unavailable, a regimen that is different from the medications the source currently uses can be used for the initial dose. Choose two nucleoside reverse transcriptase inhibitors and a protease inhibitor, such as: • zidovudine or stavudine+ lamivudine AND nelfinavir, indinavir, amprenavir, saquinavir OR lopinavir/ritonavir • stavudine + didanosine AND nelfinavir, indinavir, amprenavir, saquinavir OR lopinavir/ritonavir • abacavir + zalcitabine AND nelfinavir, indinavir, amprenavir, saquinavir OR lopinavir/ritonavir
Exposures to **UNKNOWN** HIV status sources at **HIGHER risk** of HIV infection	**OFFER HIV NPEP** zidovudine or stavudine + lamivudine A protease inhibitor can be added if the source has multiple high HIV risk factors for HIV infection.
Exposures to **UNKNOWN** HIV status sources at **LOWER risk** of HIV infection	**CONSIDER HIV NPEP** HIV NPEP may be considered on a case-by-case basis. Zidovudine or stavudine+ lamivudine may be offered when compelling circumstances exist.

NONOCCUPATIONAL HIV PEP BY EXPOSURE CATEGORY

SEXUAL ASSAULT

Although HIV infection has been diagnosed following sexual assault, the true rate of seroconversion is unknown. Estimated probabilities of HIV infection after consensual unprotected receptive penile-anal intercourse is 0.1-3% and 0.1-0.2% for unprotected receptive penile-vaginal intercourse (22,23). HIV transmission may be greater in sexual assault because of the associated trauma and higher likelihood of STDs in sexual assault survivors and their assailants (24). The probability of transmission is not only affected by the assailant's HIV status, but also their HIV clinical status (e.g., viral load, compliance with medications, medication resistance patterns), as well as the type and frequency of sexual assault(s) involved, condom usage, transfer of ejaculate, the number of assailants, etc. Knowledge of the true HIV status of the assailant would greatly facilitate HIV NPEP decisions, but this information is typically unknown.

Candidate HIV NPEP Exposures in Sexual Assault

- Contemplate HIV NPEP when KNOWN unprotected human vaginal or anal intercourse or oral receipt of seminal or vaginal fluids or human blood occurred. HIV NPEP is likely unnecessary for other sexual acts.
- Except in the case of sexual assault of children or adolescents, HIV NPEP should, in general, not be prescribed when the survivor (or witness) cannot provide a history of body fluid exposures. However, when the history is unknown or unclear, compelling overriding circumstances (such as physical evidence of anal or vaginal penetration or a witnessed assault) may exist when HIV NPEP may be appropriately given.

Survivor Support

- Involve sexual assault advocates and/or their counterparts in all cases of sexual assault to provide emotional and social support, as well as legal and administrative guidance, and as a resource for other concerns. Advocates can be contacted 24 hours a day through the Victims of Crime Helpline at (800) 494-8100.

Guidelines for HIV NPEP After Sexual Assault

Action	Indication / Exposure	Medication
Recommend PEP	• Unprotected vaginal or anal intercourse with a **KNOWN** HIV-infected assailant • Unprotected oral sex with a **KNOWN** HIV-infected assailant when transfer of seminal or vaginal secretions occurred	• Assailant's medications are **UNKNOWN /** assailant is not using HIV medications: zidovudine or stavudine + lamivudine AND nelfinavir OR indinavir • Assailant's medication regimen is **KNOWN** or known resistance is present: discuss options with HIV specialist as soon as possible†
Offer PEP	• Unprotected vaginal or anal intercourse with an assailant whose HIV status is **UNKNOWN** *OR* is **UNKNOWN** *AND* could be at a **HIGHER*** risk of HIV infection. • Unprotected oral sex when DEFINITE transfer of seminal or vaginal secretions occurred with an assailant whose HIV status is **UNKNOWN** *OR* is **UNKNOWN** *AND* could be at a **HIGHER*** risk of HIV infection	zidovudine or stavudine + lamivudine A protease inhibitor (indinavir or nelfinavir) can be added when: • The assailant has multiple risk factors for HIV infection, AND/OR • The survivor has a sexually transmitted disease or is pregnant, AND/OR • Other compelling circumstances exist.
Consider PEP	• Unprotected vaginal or anal intercourse with an assailant whose HIV status is **UNKNOWN** *AND* could be at a **LOWER*** risk of HIV infection • Unprotected oral sex when transfer of seminal or vaginal secretions occurred with an assailant whose HIV status is **UNKNOWN** *AND* could be at a **LOWER*** risk of HIV infection	zidovudine or stavudine + lamivudine

* See overview for definitions of sources at higher and lower risk of HIV infection

† Under the advisement of a specialist knowledgeable in HIV NPEP and HIV medications, choose a medication regimen that takes into account the source's medication history and drug resistance. If this advice and information is unavailable, a regimen that is different from the medications the source currently uses can be used for the initial dose. Choose two nucleoside reverse transcriptase inhibitors and a protease inhibitor, such as:

zidovudine or stavudine + lamivudine AND nelfinavir, indinavir, amprenavir, saquinavir OR lopinavir/ritonavir
stavudine + didanosine AND nelfinavir, indinavir, amprenavir, saquinavir OR lopinavir/ritonavir
abacavir + zalcitabine AND nelfinavir, indinavir, amprenavir, saquinavir OR lopinavir/ritonavir

CONSENSUAL SEX

The estimated probabilities for HIV seroconversion after consensual unprotected receptive are 0.1-3% for penile-anal intercourse and 0.1-0.2% for unprotected receptive penile-vaginal intercourse (22,23). The probability of transmission from a consensual sexual encounter is modulated by the partner's HIV status, their HIV clinical status if HIV infected (e.g., viral load, compliance with medications, medication resistance patterns), and the type and frequency of sexual act(s) involved, condom usage, transfer of ejaculate, etc. Knowledge of the partner's HIV status can be crucial to HIV NPEP decisions. Availability of this knowledge is variable; not all persons know the HIV status of their partners, nor do the partners necessarily know their own status.

Consensual Sex HIV NPEP Cautions

- Patients must be made aware that HIV NPEP is not a substitution for primary HIV prevention.
- Patients desiring pregnancy in HIV serodiscordant relationships must be counseled that HIV NPEP should not be used as a pre-prophylaxis measure.
- Usage of multiple rounds of HIV NPEP is not encouraged and likely reflects a failure of primary HIV prevention and counseling; behavioral interventions should instead be enacted.

Candidate HIV NPEP Exposures in Consensual Sex

- Contemplate HIV NPEP when KNOWN unprotected human vaginal or anal intercourse, oral receipt of seminal or vaginal fluids or human blood occurred. HIV NPEP is likely unnecessary for other sexual acts.
- HIV NPEP should, in general, not be prescribed when the patient cannot provide a history of body fluid exposures.

Guidelines for HIV NPEP After Consensual Sex

Action	Indication / Exposure	Medication
Recommend PEP	• Unprotected vaginal or anal intercourse with a **KNOWN** HIV-infected partner • Unprotected oral sex with a **KNOWN** HIV-infected partner when transfer of seminal or vaginal secretions occurred	• Partner's medications are **UNKNOWN /** partner is not using HIV medications: zidovudine or stavudine + lamivudine AND nelfinavir OR indinavir • Partner's medication regimen is **KNOWN** or known resistance is present: discuss options with HIV specialist as soon as possible†
Offer PEP	• Unprotected vaginal or anal intercourse with a partner whose HIV status is **UNKNOWN** *OR* is **UNKNOWN** *AND* could be at a **HIGHER*** risk of HIV infection • Unprotected oral sex when DEFINITE transfer of seminal or vaginal secretions occurred with an partner whose HIV status is **UNKNOWN** *OR* is **UNKNOWN** *AND* could be at a **HIGHER*** risk of HIV infection	zidovudine or stavudine + lamivudine A protease inhibitor (indinavir or nelfinavir) can be added when: • The partner has multiple risk factors for HIV infection, AND/OR • The survivor has a sexually transmitted disease or is pregnant, AND/OR • Other compelling circumstances exist.
Consider PEP	• Unprotected vaginal or anal intercourse with a partner whose HIV status is **UNKNOWN** *AND* could be at a **LOWER*** risk of HIV infection • Unprotected oral sex when transfer of seminal or vaginal secretions occurred with a partner whose HIV status is **UNKNOWN** *AND* could be at a **LOWER*** risk of HIV infection	zidovudine or stavudine + lamivudine

* See overview for definitions of sources at higher and lower risk of HIV infection

† Under the advisement of a specialist knowledgeable in HIV NPEP and HIV medications, choose a medication regimen that takes into account the source's medication history and drug resistance. If this advice and information is unavailable, a regimen that is different from the medications the source currently uses can be used for the initial dose. Choose two nucleoside reverse transcriptase inhibitors and a protease inhibitor, such as:

zidovudine or stavudine + lamivudine AND nelfinavir, indinavir, amprenavir, saquinavir OR lopinavir/ritonavir
stavudine + didanosine AND nelfinavir, indinavir, amprenavir, saquinavir OR lopinavir/ritonavir
abacavir + zalcitabine AND nelfinavir, indinavir, amprenavir, saquinavir OR lopinavir/ritonavir

NONOCCUPATIONAL NEEDLESTICK AND SHARP INJURIES

HIV seroconversion following a needlestick injury is uncommon. Although no estimates for HIV seroconversion exist for community, nonoccupational (non-healthcare) needlestick and sharp injuries, the estimated risk for occupational (healthcare) needlestick injuries is approximately 0.2 to 0.5% (4). HIV seroconversion following a needlestick injury from an HIV-infected person is likely greater when a deep injury occurred, a hollow-bore needle or sharp was involved, there was visible blood on the needle or sharp prior to the injury, large volumes of blood were transferred, the needle or sharp object was used in an artery or vein, and/or the HIV infected source has a high viral load. Community (non-healthcare/nonoccupational) exposures may differ since the nature of the exposures may not be similar and the prevalence of HIV-infected sources may vary widely. The efficacy of HIV NPEP in the healthcare setting for needlestick injuries is suggested by the Cardo et al. study (5). No efficacy studies are available outside that environment.

Candidate HIV NPEP Exposures after Needlestick and Sharp Injuries

- Not all needlestick and sharp injuries necessitate HIV NPEP provision. HIV NPEP should be contemplated when an uninfected person is injured by a sharp object that could potentially transmit HIV.
- HIV NPEP should, in general, not be prescribed when there was no known or clear history or evidence of an injury or when the injury or the sharp object could not possibly transmit HIV.

Guidelines for HIV NPEP after Needlestick and Sharp Injuries

Action	Indication / Exposure	Medication
Recommend PEP	Needlestick or sharp injuries that involve penetration of the skin or mucous membranes with known or possible transfer of blood or potentially HIV-infected body fluids from a source **KNOWN** to be HIV infected	• Source's medications are **UNKNOWN** / source is not using HIV medications: zidovudine or stavudine + lamivudine AND nelfinavir OR indinavir • Source's medication regimen is **KNOWN** or known resistance is present: discuss options with HIV specialist as soon as possible†
Offer PEP	Needlestick or sharp injuries that involve penetration of the skin or mucous membranes with known or possible transfer of blood or potentially HIV-infected body fluids from a source (a human or an object) whose HIV status is **UNKNOWN**, but could be could be at a **HIGHER*** risk of HIV infection	zidovudine or stavudine + lamivudine A protease inhibitor (indinavir or nelfinavir) can be added when the source has multiple risk factors for HIV infection, and/or other compelling circumstances exist.
Consider PEP	Needlestick or sharp injuries that involve penetration of the skin or mucous membranes with known or possible transfer of blood or potentially HIV-infected body fluids from a source (a human or an object) whose HIV status is **UNKNOWN**, but could be at a **LOWER*** risk of HIV infection	zidovudine or stavudine + lamivudine

* See overview for definitions of sources at higher and lower risk of HIV infection

† Under the advisement of a specialist knowledgeable in HIV NPEP and HIV medications, choose a medication regimen that takes into account the source's medication history and drug resistance. If this advice and information is unavailable, a regimen that is different from the medications the source currently uses can be used for the initial dose. Choose two nucleoside reverse transcriptase inhibitors and a protease inhibitor, such as:

zidovudine or stavudine + lamivudine AND nelfinavir, indinavir, amprenavir, saquinavir OR lopinavir/ritonavir
stavudine + didanosine AND nelfinavir, indinavir, amprenavir, saquinavir OR lopinavir/ritonavir
abacavir + zalcitabine AND nelfinavir, indinavir, amprenavir, saquinavir OR lopinavir/ritonavir

INJECTING DRUG USE

HIV seroconversion following injecting drug use is estimated to be 0.67% per episode of injecting needle or syringe sharing (18). Seroconversion is more likely with multiple exposures, and when injecting drug paraphernalia sharing occurs in an area of high HIV prevalence. Reported experience with HIV NPEP following injecting drug use has been limited.

Candidate HIV NPEP Exposures after Injecting Drug Use

- Not all injecting drug exposures necessitate HIV NPEP provision. HIV NPEP should be contemplated when an uninfected person shares injecting drug paraphernalia (needles, syringes, and other paraphernalia, e.g. cotton, cookers) with another person. HIV NPEP should, in general, not be prescribed when there was no known or clear history or evidence of such an exposure.
- HIV NPEP for injecting drug users is probably best provided in the context of reducing or eliminating risky exposures, e.g., cessation of needle sharing.

Guidelines for HIV NPEP after Injecting Drug Use

Action	Indication / Exposure	Medication
Recommend PEP	Injecting drug paraphernalia sharing with a source **KNOWN** to be HIV infected	• Source's medications are **UNKNOWN** / source is not using HIV medications: zidovudine or stavudine + lamivudine AND nelfinavir OR indinavir • Source's medication regimen is **KNOWN** or known resistance is present: discuss options with HIV specialist as soon as possible†
Offer PEP	Injecting drug paraphernalia sharing with a person whose HIV status is **UNKNOWN**	zidovudine or stavudine + lamivudine AND indinavir OR nelfinavir

† Under the advisement of a specialist knowledgeable in HIV NPEP and HIV medications, choose a medication regimen that takes into account the source's medication history and drug resistance. If this advice and information is unavailable, a regimen that is different from the medications the source currently uses can be used for the initial dose. Choose two nucleoside reverse transcriptase inhibitors and a protease inhibitor, such as:

zidovudine or stavudine + lamivudine AND nelfinavir, indinavir, amprenavir, saquinavir OR lopinavir/ritonavir
stavudine + didanosine AND nelfinavir, indinavir, amprenavir, saquinavir OR lopinavir/ritonavir
abacavir + zalcitabine AND nelfinavir, indinavir, amprenavir, saquinavir OR lopinavir/ritonavir

UNUSUAL EXPOSURES TO BODY FLUIDS

Patients may present after unusual exposures to blood and body fluids that are not covered under other sections in these guidelines. Most exposures will not require HIV NPEP. A few exposures to certain body fluids to non-intact skin or mucous membranes may necessitate an evaluation for the appropriateness of HIV NPEP. Given the rarity of these exposures, estimates cannot be made of the likelihood of HIV transmission.

Some Body Fluids That May Or Are Known To Transmit HIV (4)

- Amniotic fluid
- Cerebrospinal fluid
- Exudative or other tissue fluid from burns or skin lesions
- Human breast milk
- Pericardial fluid
- Peritoneal fluid
- Pleural fluid
- Synovial fluid
- Unfixed human tissues and organs

HIV NPEP is NOT indicated for feces, sputum, saliva, urine or vomit exposures, except perhaps when blood is visibly present in these body fluids.

Guidelines for HIV NPEP after Unusual Exposures to Body Fluids		
Action	**Indication / Exposure**	**Medication**
Recommend PEP	Exposures from potentially HIV-infected body fluids (as above), mucous membranes, or to non-intact skin from a source **KNOWN** to be HIV infected	• Source's medications are **UNKNOWN /** source is not using HIV medications: zidovudine or stavudine + lamivudine AND nelfinavir OR indinavir • Source's medication regimen is **KNOWN** or known resistance is present: discuss options with HIV specialist as soon as possible†
Offer PEP	Exposures from potentially HIV-infected body fluids (as above) to non-intact skin and mucous membranes from a source whose HIV status is **UNKNOWN**, but could be could be at a **HIGHER*** risk of HIV infection	zidovudine or stavudine + lamivudine. A protease inhibitor can be added when the source has multiple risk factors for HIV infection or other compelling circumstances exist.
Consider PEP	Exposures from potentially HIV-infected body fluids (as above) to non-intact skin and mucous membranes from a source whose HIV status is **UNKNOWN**, but could be at a **LOWER*** risk of HIV infection	zidovudine or stavudine + lamivudine

* See overview for definitions of sources at higher and lower risk of HIV infection

† Under the advisement of a specialist knowledgeable in HIV NPEP and HIV medications, choose a medication regimen that takes into account the source's medication history and drug resistance. If this advice and information is unavailable, a regimen that is different from the medications the source currently uses can be used for the initial dose. Choose two nucleoside reverse transcriptase inhibitors and a protease inhibitor, such as:

zidovudine or stavudine + lamivudine AND nelfinavir, indinavir, amprenavir, saquinavir OR lopinavir/ritonavir
stavudine + didanosine AND nelfinavir, indinavir, amprenavir, saquinavir OR lopinavir/ritonavir
abacavir + zalcitabine AND nelfinavir, indinavir, amprenavir, saquinavir OR lopinavir/ritonavir

NONOCCUPATIONAL HIV PEP DOSAGES, ADVERSE EFFECTS, IMPORTANT INTERACTIONS AND CAUTIONS

NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS

MEDICATION	DOSAGE	COMMON ADVERSE EFFECTS	POTENTIAL DRUG INTERACTIONS AND CAUTIONS
zidovudine (AZT/ZDV)	> 12 yo: 300 mg BID 3 mo-12 yo: 160 mg/m2 q6h Neonates: 2 mg/kg	Nausea, myalgia, headaches, insomnia. Major toxicity: bone marrow suppression, anemia, neutropenia.	Caution: Avoid in patients taking bone marrow suppresive drugs or therapy. *Do not give with stavudine.*
lamivudine (Epivir/3TC)	> 16 yo: 150 mg BID 3 mo-16 yo: 4 mg/kg BID Neonates: 2 mg/kg	Fatigue, headache, weakness, nausea, vomiting, diarrhea.	
didanosine (ddI/Videx)	Pediatrics: 90-150 mg/m2 BID Adolescents and Adults: >60 kg: 200 mg BID <60 kg: 125 mg BID	Dry mouth, altered taste, nausea, diarrhea. Major toxicity: peripheral neuropathy and pancreatitis.	*Do not give with zalcitabine.* Caution: Avoid in patients with a history of pancreatitis, very high triglyceride levels, alcohol abuse.
stavudine (d4T/Zerit)	>60 kg: 40 mg BID <60 kg: 30 mg BID <30 kg: 1 mg/kg BID	Headache, rash, gastrointestinal distress. Major toxicity: peripheral neuropathy.	*Do not give with zalcitabine.*
zalcitabine (ddC/Hivid)	Pediatrics: 0.005-0.01 mg/kg q8h Adults: 0.75 mg q8h	Headache, malaise gastrointestinal distress. Major toxicity: Painful sensorimotor peripheral neuropathy (common).	*Do not give with didanosine or stavudine.*

PROTEASE INHIBITORS

indinavir (Crixivan)	>16 yo: 800 mg q8h *Not recommended for <16 yo*	Nausea, headache, dyspepsia, diarrhea, flatulence, gas, hyperglycemia. Major toxicity: nephrolithasis.	*Do not give with astemizole,cisapride, ergot alkaloids, midazolam, rifampin, terfenadine, triazolam.* Caution: Must reduce rifabutin dose if used concomitantly.
nelfinavir (Viracept)	2-13 yo: 20-30 mg/kg TID > 13 yo: 1250 mg BID	Diarrhea, nausea, dyspepsia.	*Do not give with astemizole, cisapride, ergot alkaloids, midazolam, rifampin, terfenadine, triazolam.* Caution: Must reduce rifabutin dose if used concomitantly. Caution: May reduce the efficacy of birth control pills.

GENERAL COMMENTS ON ADVERSE SIDE EFFECTS

All antiretroviral medications that may be used for HIV NPEP can produce adverse side effects. The most common side effects are primarily gastrointestinal (e.g., nausea, diarrhea, dyspepsia) or constitutional (e.g., fatigue, malaise). Some drugs have unique side-effect profiles and interactions, and should be used with caution in some circumstances, or not at all. Parkin et al. observed higher rates of reported adverse side effects in patients taking antiretroviral medications for occupational HIV PEP than those taking them for their HIV infection (25). These scientists attributed the difference to the anxiety associated with taking occupational HIV PEP because of the fear of becoming HIV infected. Also, higher rates of adverse side effects have been noted in healthcare personnel prescribed higher than currently recommended doses of zidovudine (26). All side effects of HIV NPEP medications (except for nevirapine, which is not recommended for HIV NPEP) appear to be reversed when the pills are discontinued (27, 28). Most of the side effects reduce over time. Therefore, patients should be reassured that the side effects are not permanent, may be related to the trauma and uncertainty of becoming HIV infected, will improve during their medication course, and can be avoided in some circumstances (e.g. taking the medication with food—except indinavir, drinking plenty of water, taking the medications with an anti-emetic, etc.)

RECOMMENDATIONS FOR NONOCCUPATIONAL HIV PEP FOLLOW UP

The recommendations provided in this section may be used as a base for more extensive follow-up programs, especially those that involve improved methods of HIV risk reduction. Coordinated care with counselors and ancillary specialists is strongly recommended.

The type and timing of follow up required by patients who were evaluated for HIV NPEP depends upon whether or not they accepted or needed HIV NPEP. Patients whose exposure did NOT necessitate HIV NPEP provision may receive follow up from their primary healthcare provider and any ancillary providers or services as necessary. Patients who did accept HIV NPEP should be reevaluated within 72 hours by a healthcare provider knowledgeable and experienced with HIV NPEP. Patients who declined HIV NPEP when it was recommended or appropriately offered should be reevaluated within 24 hours by the same type of provider.

HIV NPEP ACCEPTED BY PATIENT

Initial Follow-up Visit within 72 hours

1. Re-evaluation of HIV NPEP indications and medications

    a. Determine if any new information about the exposure and source are available

        i. Attempt to delineate if the exposure qualified for HIV NPEP. If HIV NPEP was not indicated, discontinue HIV NPEP.
        ii. Determine if any information is available about the source and if the source can be contacted or tested. The source may need to be contacted directly. If contacting the source is hazardous to the patient or to the healthcare provider, attempt to gain the required information through a third party (e.g., police or corrections facility).

            (a) Source is not HIV infected (per a confirmed HIV test): Discontinue HIV NPEP.
            (b) Source is HIV infected: Adjust the medications as necessary.
            (c) Source can be tested: Initiate HIV testing and then re-evaluate the need for HIV NPEP and the medications provided when the test results are available. Rapid HIV testing (within 24 hours) is preferable.
            (d) Source's risk profile is available: Evaluate the source's risk profile and adjust medication regimen as indicated.

    b. If no new information is available and HIV NPEP was indicated by the exposure, re-evaluate the medications prescribed and adjust as necessary.
    c. Determine if initial laboratory testing was performed. If not, obtain the appropriate tests. If the tests were performed, review the results and adjust the medication regimen as necessary.

2. Risk reduction counseling

    a. Needlestick or sharp injuries: Counsel and instruct patient on ways to avoid these injuries (e.g., wearing sharp-permeable gloves, not touching medical waste). Intervention may also involve consultation with occupational health advisors and HEALTH.
    b. Sexual assault: In coordination with sexual assault counselors, attempt to provide instruction, support and resources on preventing further sexual assault.
    c. Consensual sex: HIV NPEP following consensual sex should be considered a failure of primary prevention modalities. Any barrier to the patient using primary prevention (e.g., lack of condom usage, substance abuse) should be addressed. Remind each patient to use safer sexual practices.
    d. Injecting drug use: Counsel the patient not to share drug paraphernalia and instruct him/her on safer needle usage (e.g., bleaching). Enrollment of the patient in a substance abuse cessation program is highly encouraged and preferred.

e. Miscellaneous exposures: Counsel on avoiding these exposures as indicated.

3. Medication provision

a. HIV NPEP course: A two-week supply of medications is recommended.
b. Anti-emetics: A short course may be prescribed.
c. STD prophylaxis or treatment: Prophylaxis or treat against gonorrhea, chlamydia and trichomonas as needed.
d. Vaccinations: Hepatitis B vaccination should be given to those not already vaccinated. Hepatitis A vaccination is recommended for those who had a sexual exposure.

Two Week Follow-up Visit

1. Reevaluation of medications: If any new information regarding the source's HIV status or HIV risk is available, adjust medications as necessary.
2. Assessment of adverse side effects

a. Evaluate the patient for the presence of any signs or symptoms attributable to adverse side effects of the medication. Instruct the patient that some of these symptoms may be due to the anxiety of taking HIV NPEP or stress regarding the exposure.
b. Discontinue HIV NPEP for any signs or symptoms of severe or life-threatening adverse side effects.
c. Encourage the use of anti-emetics, a change in eating habits (e.g., eating a small snack with medications, increased water intake, etc.) and a change of the time taking medications.
d. Reassure the patient that the unpleasant side effects of the medications will likely become less during their 28-day course.
e. Perform complete blood count, chemistry panel, and liver-associated enzymes (if a protease inhibitor was prescribed) testing to monitor toxicity, and pregnancy testing for females of childbearing age.

3. Analysis of laboratory testing

a. Discontinue HIV NPEP if the patient is HIV infected. Treat/refer accordingly.
b. Discontinue HIV NPEP if either renal failure (creatinine > 2.0) or severe anemia (hemoglobin < 7.0) are present.
c. Provide any treatment or referral as necessary for any STD or hepatitis infections. Treat and test partners as indicated.
d. Refer or treat for any other condition (e.g., diabetes, pregnancy) noted from the baseline testing.
e. Refer to a primary care provider any patient who is not HIV infected and whose HIV NPEP was discontinued. Refer any pregnant patient to an obstetrician-gynecologist knowledgeable in the care of patients taking HIV medications.

4. Evaluate for acute HIV infection.
5. Risk reduction counseling: Continue to reinforce HIV exposure risk reduction.
6. Medication provision: A two-week supply of HIV NPEP is recommended. Other medications (e.g., STD treatment, anti-emetics) should also be provided.
7. Patient instructions: Review the patient instructions with the patient.

Six Week Visit

1. Assess the patient for adverse side effects attributable to HIV NPEP: Perform additional laboratory testing or evaluations as indicated.
2. Laboratory testing:

    a. For all patients who took HIV NPEP: complete blood count, chemistry panel, HIV antibody screening. Liver-associated enzyme testing should be performed for any patient who took at least a two-week course of a protease inhibitor. Follow up results with patients as soon as possible and treat/refer when indicated.
    b. Additional testing: pregnancy testing for any female of childbearing age. Refer to an obstetrician-gynecologist knowledgeable in the care of patients taking HIV medications if the patient is pregnant.

3. Evaluate for acute HIV infection.
4. Risk reduction counseling: Continue to reinforce HIV risk reduction.
5. Hepatitis B vaccination: Second dose should be provided four weeks after the first dose.

Additional Visits

1. HIV Testing: Recommended at three and six months postexposure.
2. Risk reduction counseling: Continue to reinforce HIV risk reduction.
3. Hepatitis B vaccination: Third dose should be provided six months after the first dose. Those receiving a Hepatitis A vaccination should receive their second dose six months after the first dose.

HIV NPEP DECLINED BY PATIENT

Any patient who declined HIV NPEP when it was recommended or offered appropriately should be encouraged to follow up within 24 hours with a healthcare provider knowledgeable in HIV NPEP provision. The indications for HIV NPEP can then be reviewed. If HIV NPEP is indicated, it may be recommended or offered again as appropriate. Any barriers that hamper a patient's willingness to accept HIV NPEP should be addressed and rectified (if possible). If the patient again declines HIV NPEP, the patient may be encouraged to re-evaluate this decision and to return for another evaluation within 72 hours of the exposure. If the patient accepts this evaluation, HIV NPEP and reasons for declining it can be reviewed and discussed again at that visit. HIV NPEP may be started then if the patient agrees. The patient should be reminded that beginning HIV NPEP 72 hours following the exposure might not be beneficial.

HIV, hepatitis B and C, pregnancy and STD testing should be performed for any patient who declines HIV NPEP. The patient should undergo follow up for these tests as required. Additional HIV testing should occur at six weeks, three and six months postexposure. Hepatitis B vaccination should also be provided to non-immune or non-hepatitis B-infected persons. Hepatitis A vaccinations may be offered to patients who had a sexual exposure. All patients should receive HIV risk reduction counseling. Referral to ancillary providers should be offered, as indicated.

CRITERIA FOR DISCONTINUING HIV NPEP

- Completion of 28 days of HIV NPEP
- Development of life-threatening or severe adverse medication effects
- Continued engagement in risky HIV practices
- Persistent failure to take medications as directed
- Patient's voluntary cessation despite counseling regarding risks of stopping treatment
- Patient becomes or is HIV infected
- Laboratory verification that the source is currently NOT HIV infected

PROFESSIONAL ASSISTANCE WITH NONOCCUPATIONAL HIV PEP

HIV specialists

HIV specialists should be consulted when a healthcare practitioner requires additional expertise, such as in the care of patients who have exposures to known HIV infected sources and in the care of pediatric and pregnant patients, or when unusual or atypical exposures or circumstances occur. An HIV specialist is a licensed practicing physician trained in the specialty of infectious diseases and internal medicine or involved in the clinical management of patients with HIV, is trained in HIV NPEP provision through formal residency or fellowship training and hands-on clinical work, and is participating in HIV-specific continued medical education. A pediatric HIV specialist is similarly trained but has additional expertise in the care of HIV-infected adolescents and children. Any HIV specialist who will be seeing patients evaluated for HIV NPEP or advising other clinicians on HIV NPEP issues should have a working knowledge of these guidelines, and have a thorough understanding of current HIV NPEP research and recommendations.

Obstetrician-gynecologists

An obstetrician-gynecologist should be involved in the care of any female who was evaluated for HIV NPEP who: (1) was sexually assaulted, (2) is pregnant, (3) is breast feeding, (4) has a sexually transmitted disease, (5) is HIV infected, and/or (6) has any other gynecologic problem or condition that needs to be addressed. Any obstetrician-gynecologist involved in the care of HIV NPEP patients should be knowledgeable of these guidelines and of the gynecologic and obstetrical care of HIV-infected women.

Adult sexual assault/abuse counselors

Patients who have been sexually assaulted need immediate support following the assault by a trained sexual assault counselor or advocate. Follow-up visits with the counselor/advocate should be encouraged and facilitated. The counselor/advocate should be free (with patient consent) to contact the patient's healthcare provider with any patient-related concerns.

Substance abuse counselors/Addiction Medicine specialists

Any patient who abuses alcohol or other drugs should be referred to an appropriate counselor who is knowledgeable of these guidelines as part of a means of reducing further HIV risk. Follow-up visits with the counselor/advocate should be encouraged and facilitated. The counselor/advocate should be free (with patient consent) to contact the patient's healthcare provider with any patient-related concerns. Addiction medicine specialists may need to be involved in the care of selected patients.

Adolescent and child sexual abuse/assault specialists

Any patient 18 years of age or younger who was sexually assaulted or abused should be under the care of a specialist in adolescent and child sexual abuse/assault who is trained and knowledgeable with HIV NPEP. Care should be coordinated with such specialists upon the patient's initial evaluation for HIV NPEP. Further coordination of care should continue throughout follow up.

SPECIAL CONSIDERATIONS

Children/Adolescents

HIV NPEP indications are generally the same as for adults. The primary differences are in the medications and dosing regimens used, support services/consultations needed, informed consent issues, and the necessity for parental/guardian/caretaker involvement.

Medications: (1) Weight-based formulations are available for most medications. (2) Combivir (zidovudine/lamivudine) is not available for patients younger than 16 years old. (3) Indinavir (Crixivan) is not recommended for patients 16 years or younger. (4) No specific age determinations are available to distinguish pediatrics from adolescents for didanosine, stavudine, and zalcitabine. (5) Oral solutions, syrups, and powders are available for most medications.

Support services/consultations: (1) A pediatric HIV specialist should be involved in every patient under 16 years old who receives HIV NPEP. Consultation with the specialist must not delay HIV NPEP provision, however. (2) Specialists in child sexual abuse and assault should be involved in the care of any patient under 16 years old who is a survivor of a possible sexual assault or abuse. Patients in this age group who present after reported consensual sex should also be referred to such specialists, as coercion or occult abuse may have occurred.

Informed consent: Emancipated minors may consent for HIV NPEP. For all other pediatric patients, a parent, legal guardian, or legal caretaker must consent to HIV NPEP provision. For all pediatric patients, involvement of the parent, legal guardian, or legal caretaker is essential for successful completion of HIV NPEP. A recent study of HIV NPEP in pediatrics observed greater compliance with completion of HIV NPEP in patients whose parents or guardians were supportive and active in their child's HIV NPEP course (29). Effective communication among the healthcare provider and the parent/guardian/caretaker and patient can insure better compliance.

Child sexual abuse/assault: HIV NPEP may be indicated when known unprotected intercourse occurred between a child and an abuser/assailant who is at risk for HIV infection. HIV NPEP is not recommended when there is no evidence that unprotected intercourse occurred (e.g., no clear history and no physical evidence), the sexual encounter could not result in an HIV infection, when the event occurred greater than 72 hours prior to an evaluation for HIV NPEP, or when the abuser/assailant is not at risk for HIV infection. Consultation with experts in child sexual abuse is strongly encouraged in all cases of child sexual abuse/assault. All healthcare providers are mandated by state law to immediately report to the appropriate authorities any suspicion of child sexual abuse/assault.

Pregnancy

HIV NPEP indications during pregnancy are the same as during other times. However, pregnant women must be informed of the potential risks and unknown benefits of HIV NPEP during pregnancy. Although it is known that perinatal antiretroviral medications can reduce the incidence of HIV infections in infants, it is not known if HIV NPEP is similarly efficacious. There are no studies that document the risks or benefits of HIV NPEP in pregnancy. Pregnant women should be free to decline HIV NPEP if they believe the risks outweigh the benefits. Any pregnant patient who accepts HIV NPEP must be under the care of an HIV specialist and obstetrician experienced with managing HIV medications in pregnant females.

Intentional HIV Exposures

A suicide attempt with HIV infected blood (resulting in HIV seroconversion despite HIV NPEP) and an attempted criminal intentional injection with HIV infected blood have been reported (30). Given that an estimated 95% of transfusions from one unit or more of HIV infected blood and blood products transmit HIV (18), it is unlikely that oral antiretroviral medications will be effective after an intentional injection or transfusion. An oral regimen with zidovudine + lamivudine AND indinavir or nelfinavir may be initiated while preparations are made for intravenous therapy. An HIV specialist knowledgeable of HIV NPEP should be immediately involved in the care of such patients.

SAMPLE NONOCCUPATIONAL HIV PEP PATIENT INSTRUCTIONS

As you know, you may have been exposed to the Human Immunodeficiency Virus (HIV). You will be given medicine, which may prevent your becoming infected with HIV. Here are some important things you should know:

1. **Your chance of becoming infected is probably small.** The medications you will be taking should keep you from becoming infected, but there is no guarantee that they will work. We hope they help you.

2. **See a doctor.** It is important that you take these drugs under the supervision of an experienced doctor. See this doctor within three days of starting your medications. Your doctor may refer you to a specialist, if needed.

3. **Take medications on time and for the full four weeks**. During this stressful time, we encourage you to do things you enjoy and get plenty of rest and exercise. You may want to share your thoughts with a friend or loved one. You may also find it helpful to visit a counselor, therapist or social worker.

4. **Do not have sexual intercourse while taking these medications.** Do not donate blood, body tissue, milk or sperm. If you are female, avoid pregnancy until your HIV status is known. If you are a nursing mother, do not nurse your baby until your lab tests confirm that you are not HIV infected.

5. **These medications will not protect you from HIV if you expose yourself to the virus again.** Preventing HIV infection, especially through safer sex, is best.

6. **Are you sure the person who exposed you to HIV really has HIV?** If you are able to safely contact the person, ask if he/she has HIV and what medications he/she is taking. If he/she has had an HIV test, ask when and where and if you can get a copy of the results. If you cannot safely get this information, tell your doctor.

7. **These medications have side effects** and may make you feel ill:

    - **Zidovudine** (AZT/ZDV) can cause nausea, upset stomach, loss of appetite, vomiting, headache and weakness. Take each dose with a full glass of water. Zidovudine can be taken with or without food.

    - **Lamivudine** (3TC/Epivir) can cause headache, weakness, nausea, vomiting and diarrhea. Take each dose with a full glass of water. Lamivudine can be taken with or without food.

    - **Stavudine** (D4T/Zerit) can cause pain, tingling or numbness, nausea and headache. Take each dose with a full glass of water. Stavudine can be taken with or without food.

    - **Didanosine** (DDI/Videx) can cause fatigue, pain, tingling or numbness, dry mouth, nausea, diarrhea, stomach pain or discomfort. Take on an empty stomach, one hour before or two hours after a meal. Do not drink alcohol while taking didanosine.

    - **Indinavir** (Crixivan) can cause gas, upset stomach, headache, diarrhea and kidney stones. Take on an empty stomach, one hour before or two hours after a meal. If indinavir upsets your stomach, take it with a low-fat, low-protein, low-calorie snack. Drink at least six, 8 ounce glasses of water per day to prevent kidney stones.

    - **Nelfinavir** (Viracept) can cause gas, upset stomach, diarrhea, headache and fever. Take with a meal or light snack.

Side effects other than those listed here may also occur. If you experience side effects, call your doctor. Do not stop taking the medications until your doctor tells you to do so. If you experience an allergic reaction including difficulty breathing; closing of your throat; swelling of your lips, tongue, or face; or hives, stop taking the medications and seek emergency medical attention.

NONOCCUPATIONAL HIV PEP RESOURCE LIST

National Resources

HIV NPEP Information

HIV/AIDS Treatment Information Service
www.hivatis.org

*Provides information on HIV and AIDS treatment

Needlestick!
University of California, Los Angeles, Emergency Medicine Center
www.needlstick.mednet.ucla.edu

*Provides information regarding occupational exposures

National Clinicians' Postexposure Prophylaxis Hotline (PEPline)
University of California, San Francisco/San Francisco General Hospital
(888) 448-4911
www.ucsf.edu/hivcntr

*Provides advice regarding possible HIV exposures

HIV NPEP Research and Data Collection

Food and Drug Administration
(800) 332-1088
MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20857
www.fda.gov/medwatch

*Collects data on unusual or severe toxicity to antiretroviral medications

HIV Antiretroviral Pregnancy Registry
(800) 258-4263
Fax: (800) 800-1052
Research Park, 1011 Ashes Drive, Wilmington, NC 28405
800-258-4263; Fax: 800-800-1052
www.apregistry.com

*Does not provide advice. Collects information regarding HIV medication use during pregnancy

National Nonoccupational HIV PEP Registry
(877) HIV-1PEP
Fax: (877) HIV-7PEP
HIV NPEP Registry, 44 Farnsworth St, 7th Floor, Boston, MA 02217
www.hivpepregistry.org

*Does not provide advice. Collects data on HIV NPEP usage.

Rhode Island Resources

Sexual Assault/Abuse

Child Safe Clinic
(401) 444-3996
Hasbro Children's Hospital
*Provides assistance with, evaluation and follow-up of child abuse/assault patients

Rhode Island Department of Children, Youth and Families
(800) RI-CHILD
*Child abuse reporting hotline that provides information and referrals

Sexual Assault and Trauma Resource Center
Rhode Island Children's Advocacy Center
(401) 421-4100 or (800) 494-8100
Fax: (401) 454-5565
300 Richmond Street, Suite 205, Providence, RI, 02903-4222
www.satrc.org
*Provides counseling and advocacy for survivors of sexual abuse and assault

Victims of Crime Helpline
(800) 494-8100
* Provides support, information and referrals to victims and professionals, accompaniment to hospitals, police stations, and court

Women and Infants Hospital of Rhode Island Women's Primary Care Center
(401) 274-1122 (extension 2735)
*Provides follow up and consultation for sexual assault and abuse survivors

Hospitals in Rhode Island with HIV Specialists for HIV/AIDS and HIV NPEP

Hasbro Children's Hospital
(401) 444-8360
Pediatric HIV program

Kent Hospital
(401) 885-5409
Infectious Diseases consultants

Landmark Hospital
(401) 766-3428
Infectious Diseases consultants

Memorial Hospital of Rhode Island
(401) 729-2545
Department of Infectious Diseases

The Miriam Hospital
(401) 793-2928
The Miriam Hospital Immunology Center

Our Lady of Fatima Hospital
(401) 456-3102
Infectious Diseases consultants

Rhode Island Hospital
(401) 444-1678 or 444-3600
HIV Clinic

Roger Williams Medical Center
(401) 456-2437
Division of Infectious Diseases

*All provide advice, consultations, and/or follow-up regarding HIV NPEP and HIV/AIDS care

Women and Infants Hospital
(401) 274-1122 (extension 2350)
Maternal and Fetal Medicine
*Provides consultation and follow up for pregnant patients on HIV NPEP or with HIV/AIDS

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