

HIV PROPHYLAXIS FOLLOWING NON-OCCUPATIONAL EXPOSURE INCLUDING SEXUAL ASSAULT

TABLES AND RECOMMENDATIONS

I. INTRODUCTION

See Figure 1.

Key Points:

Non-occupational PEP should never replace adopting and maintaining preventive behaviors and is not routinely recommended in situations in which high-risk behavior is habitually practiced.

Risk-reduction counseling is a major and essential complement to PEP.

II. PEP FOLLOWING NON-OCCUPATIONAL EXPOSURES (NPEP)

A. Assessment to Determine Whether nPEP Is Indicated

RECOMMENDATIONS:

Whenever possible, risk assessment and initiation of nPEP should occur in clinical settings where HIV prevention counseling services, as well as HIV clinical expertise, are available or are easily accessed by referral.

Patients who present for nPEP should be evaluated as soon as possible in order to initiate therapy, if indicated, within recommended time frames (see Section IV: *Timing of Initiation of PEP for All Non-Occupational Exposures*).

When deciding whether to recommend the initiation of nPEP, the clinician should assess and carefully weigh the following factors (see Table 1):

- the behavioral factors and circumstances that led to HIV exposure
- the patient's risk of HIV acquisition based on the type of exposure
- the possibility that the source is HIV-infected

The clinician should provide risk-reduction counseling and primary prevention counseling whenever someone is assessed for nPEP, regardless of whether PEP is initiated.

Non-occupational PEP should not be prescribed when there is negligible or low risk of HIV transmission (see Table 2).

Non-occupational PEP should not be used as a pre-exposure prophylactic measure to prevent HIV transmission in a woman wishing to become pregnant with an HIV-infected male partner, or as prophylaxis for any person who plans to engage in high-risk behavior.

Clinicians should provide supportive counseling and make referrals for counseling for patients for whom nPEP is not prescribed.

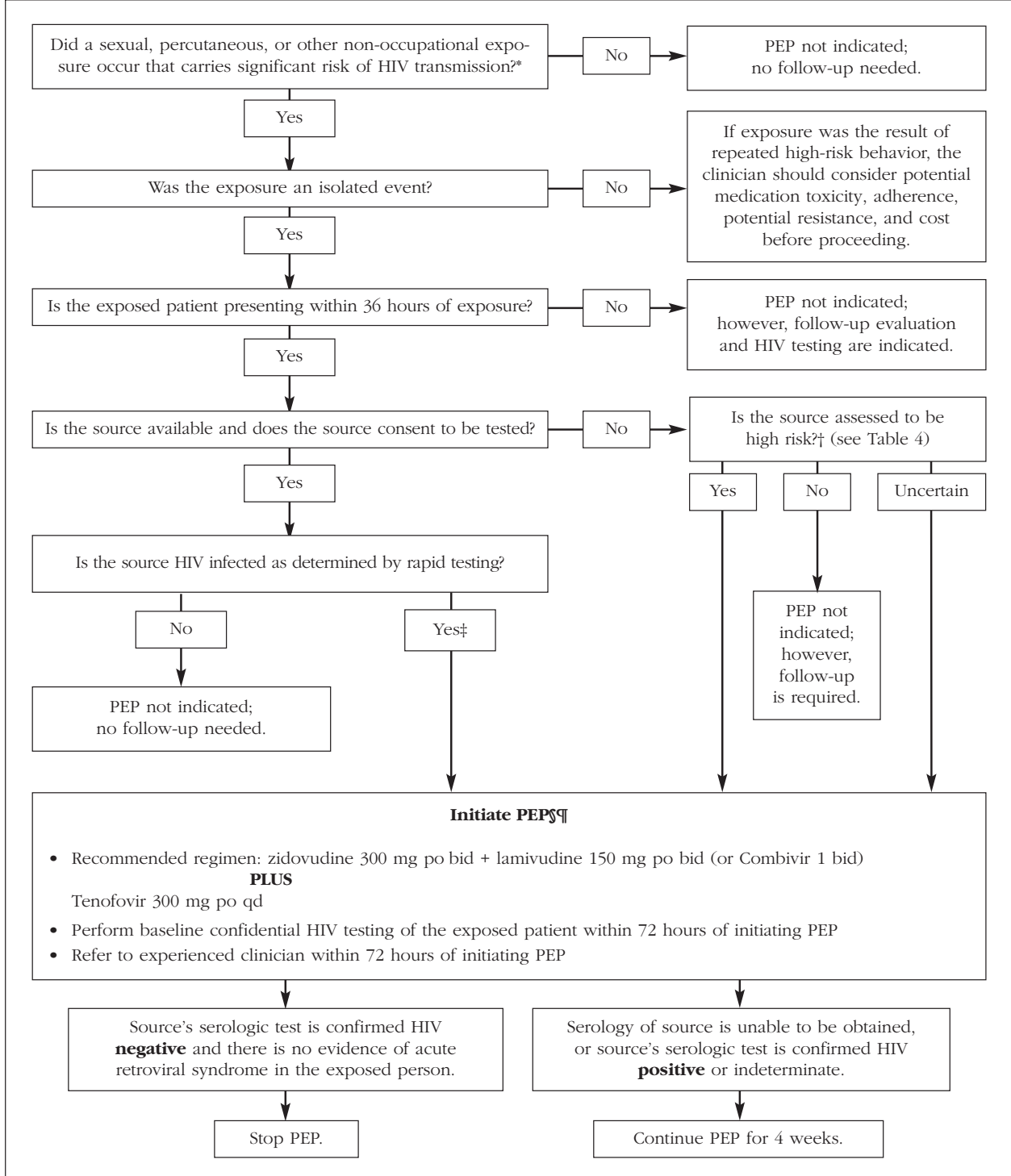
HIV Exposure Through Sexual and Drug-Using Activities

See Table 3.

3. Considering the HIV Status of the Exposure Source

See Table 4.

FIGURE 1
PEP FOLLOWING NON-OCCUPATIONAL EXPOSURE INCLUDING SEXUAL ASSAULT



* See Tables 2 and 3.

† In cases of sexual assault, the decision to initiate PEP is based on whether a significant exposure has occurred during the assault rather than on the risk behavior of the alleged assailant.

‡ If the source is known to be HIV infected, information about his/her CD4 count, viral load, ARV medication history, and history of ARV drug resistance should be obtained when possible to assist in selection of a PEP regimen.

§ If a sexual assault survivor is too distraught to engage in a discussion about the drug regimen or make a decision about whether to initiate treatment at the initial assessment, the clinician should offer a first dose of medication and make arrangements for a follow-up appointment within 24 hours to further discuss the indications for PEP.

¶ See Appendix A for dosing recommendations in patients with renal impairment.

TABLE 1
ELEMENTS OF ASSESSMENT TO DETERMINE WHETHER nPEP IS INDICATED

Risk Behavior:

- Did exposure to potentially HIV-infected blood or body fluid occur?
- Was the exposure an isolated or episodic event, or result of habitual behavior?

Degree of Transmission Risk Based on Type of Exposure:

- What was the route of exposure?
- Are factors present that are known to further increase transmission risk?

Exposure Source:

- Is the source known to be HIV infected?*
- If HIV status of the source is unknown, what is the likelihood of the source being HIV infected (see Table 4)?

* If the source is known to be HIV infected, information about his/her CD4 count, viral load, ARV medication history, and history of ARV drug resistance should be obtained when possible to assist in selection of a PEP regimen.

TABLE 2
CONSIDERATION OF nPEP ACCORDING TO THE TYPE OF RISK EXPOSURE*

Types of Exposures That Do Not Warrant nPEP	Types of Exposures That Should Prompt Consideration of nPEP
<ul style="list-style-type: none"> • Kissing • Oral-to-oral contact without mucosal damage (mouth-to-mouth resuscitation) • Human bites not involving blood • Exposure to needles or sharps not in contact with an HIV-infected or at-risk person • Mutual masturbation without skin breakdown • Oral-anal contact • Receptive penile-oral contact without ejaculation • Insertive penile-oral contact • Oral-vaginal contact without blood exposure 	<ul style="list-style-type: none"> • Unprotected receptive and insertive vaginal or anal intercourse with a source that is HIV-infected or at risk for HIV infection • Unprotected receptive penile-oral contact with ejaculation with a source that is HIV-infected or at risk for HIV infection • Oral-vaginal contact with blood exposure • Needle sharing with a source known to be HIV-infected or at risk for HIV infection • Injuries with exposure to blood from a source known to be HIV-infected or at risk for HIV infection (including needlesticks, human bites, accidents)

* Table 3 provides risk calculations for specific risk behaviors; Table 4 defines who is considered at high risk for HIV infection.

TABLE 3 ESTIMATED RISK OF HIV TRANSMISSION FOLLOWING DIFFERENT TYPES OF EXPOSURES*		
Type of Exposure	Estimated Risk	Reference
Needle-sharing exposure to an infected source	0.67% (1 in 150)	Ref. 15
Receptive anal intercourse with an infected source	0.5% (1 in 200) to 3.0% (6 in 200)	Refs. 12,13
Receptive vaginal intercourse with an infected source	0.1% (1 in 1000) to .2% (2 in 1000)	Refs. 13,14
Insertive anal intercourse with an infected source	0.065% (1 in 1500)	Refs. 13,14
Insertive vaginal intercourse with an infected source	0.05% (1 in 2000)	Refs. 13,14
Oral sex with ejaculation with an infected source	Conflicting data—however, risk is considered to be low†	Refs. 20,21

* These risk estimates depend on many factors, including source viral load, presence of STDs, and presence of ejaculate.

† It is prudent to recommend nPEP for receptive oral sex with ejaculation, although discussion about the conflicting data should occur.

TABLE 4 SOURCES THAT MAY BE AT INCREASED RISK FOR HIV INFECTION
<ul style="list-style-type: none"> • Sources with a history of multiple sexual partners • Sources with a sexually transmitted disease, particularly ulcerative diseases • Sources who are men who have sex with men • Sources with a history of needle-sharing behavior • Sources with a history of trading sex for money or drugs

B. Baseline Testing for Patients Who Present With Risk Exposures

RECOMMENDATIONS:

The clinician should perform baseline HIV testing of the exposed person. Initiation of nPEP should not be delayed pending HIV test results. Where available, rapid testing should be used.

The clinician should perform an assessment for other sexually transmitted diseases, such as chlamydia, gonorrhea, and syphilis, and should provide STD prophylaxis in sexually exposed patients.

The clinician should obtain baseline pregnancy testing for exposed women. Emergency contraception should be offered to and discussed with women at risk of pregnancy from the exposure.

C. Deciding to Recommend nPEP

RECOMMENDATIONS:

The clinician should initiate nPEP ideally within 2 hours and no later than 36 hours following exposure when an isolated exposure (sexual, needle, or trauma) has occurred, when risk-reduction practices fail, or in the instance of regretted exposure.

The clinician should discuss the following issues with the patient and should document that they were discussed before initiating a regimen:

1. the potential benefit, unproven efficacy, and potential toxicity of nPEP
2. the need for adherence
3. the need to initiate/resume risk-reduction and preventive behaviors
4. signs and symptoms of primary HIV infection
5. the need for clinical and laboratory monitoring and follow-up

The patient should agree to follow-up monitoring and initiation of interventions to reduce risk, if applicable, before the clinician initiates nPEP. All components of this discussion should be documented so that events leading to infection can be clearly identified and the efficacy of nPEP can be assessed.

D. Behavioral Intervention and Risk-Reduction Counseling

RECOMMENDATIONS:

Behavioral intervention for risk reduction should occur regardless of whether nPEP is initiated or not.

Clinicians should assess for emotional, psychological, and social factors that can contribute to risk behavior, such as depression, history of sexual abuse, and drug and alcohol use.

Clinicians should refer patients to mental health and/or substance use programs when indicated and should consider the need for intensive risk-reduction counseling services.

III. PEP FOR SEXUAL ASSAULT SURVIVORS

RECOMMENDATION:

Survivors of sexual assault should be treated in an emergency department or equivalent healthcare setting where all appropriate medical resources are available as needed.

A. Assessment to Determine Whether nPEP Is Indicated Following Sexual Assault

RECOMMENDATIONS:

When deciding whether to recommend the initiation of nPEP to the survivor, the clinician should assess and carefully weigh the following factors:

- whether or not a significant exposure has occurred during the assault
- knowledge of the HIV status of the alleged assailant
- whether the survivor is ready and willing to complete the nPEP regimen

The clinician's decision to recommend nPEP should not be influenced by the geographic location of the assault.

1. Degree of Risk Based on Type of Exposure

RECOMMENDATIONS:

Clinicians should recommend HIV nPEP to survivors when significant exposure may have occurred, as defined by direct contact of the vagina, anus, or mouth with the semen or blood of the alleged assailant, with or without physical injury,

tissue damage, or presence of blood at the site of the assault.

Non-occupational PEP should also be offered in cases of assault or trauma involving broken skin or when mucous membranes of the survivor have been in contact with blood or semen of the alleged assailant. Similarly, nPEP should be offered in cases of bites that result in visible blood.

2. Considering the HIV Status of the Alleged Assailant

RECOMMENDATIONS:

Unless the identity and HIV status of the alleged assailant has been clearly established to assist with the decision-making, nPEP should be promptly initiated when a significant risk exposure has occurred.

Even when the alleged assailant is known to be HIV infected, the decision to recommend nPEP should be based on the nature of the exposure and the survivor's ability to complete the regimen.

If prophylaxis has been initiated and the alleged assailant is found to be HIV antibody negative, then nPEP should be discontinued.

B. Recommending nPEP for Sexual Assault Survivors

RECOMMENDATIONS:

Non-occupational PEP should be initiated as soon as possible after exposure. Non-occupational PEP is unlikely to be effective more than 36 hours post-exposure (see Section IV: *Timing of Initiation of PEP*).

Starter packs of medication should be available on-site for rapid initiation of nPEP following sexual assault. Arrangements should be made to ensure that the patient receives a continued supply of medication and is referred to an HIV Specialist.

The recommendation for nPEP should be communicated simply and clearly to the patient, considering his/her emotional state and ability to comprehend the nature of ARV treatment.

If a sexual assault survivor is too distraught to engage in a discussion about the drug regimen or make a decision about whether to initiate treatment at the initial assessment, the clinician should offer a first dose of medication and make arrangements for a follow-up appointment within 24 hours to further discuss the indications for nPEP.

If a sexual assault survivor decides to initiate treatment, a follow-up visit should be scheduled within 24 hours to review the decision, evaluate initial drug tolerability, reinforce the need for adherence to the regimen, and arrange for follow-up care.

The discussion regarding initiation of nPEP should include the following:

- The potential to prevent HIV infection
- Possible side effects of the nPEP regimen
- Duration of nPEP and the monitoring schedule
- Importance of adherence to the treatment regimen to prevent nPEP failure or the development of drug resistance should infection occur

C. The Role of the Rape Crisis Counselor and Sexual Assault Examiner

RECOMMENDATIONS:

The rape crisis counselor should be an active participant in the discussion regarding HIV nPEP.

The plan for follow-up care should be discussed with the rape crisis counselor or an outreach worker who will be working with the survivor following the survivor's departure from the emergency department or equivalent healthcare setting.

Key Point:

The rape crisis counselor may play a pivotal role in helping the survivor better understand the potential benefits of prophylaxis and its side effects, the complex dosing schedule, and the importance of treatment adherence.

D. HIV Testing of the Survivor

RECOMMENDATIONS:

Clinicians should obtain blood for baseline HIV serologic testing when recommending initiation of nPEP. Prophylaxis, when indicated, should be started without waiting for the results of this test.

Refusal to undergo baseline testing should not preclude initiation of nPEP.

Key Point:

Use of rapid HIV testing technology in the setting of sexual assault should balance the potential benefit of avoiding unnecessary initiation of PEP (for a patient who has existing, undiagnosed HIV infection) against the potential harm to the emotional state of the survivor from learning of a positive test result in the immediate aftermath of having been assaulted.

IV. TIMING OF INITIATION OF PEP FOR ALL NON-OCCUPATIONAL EXPOSURES

RECOMMENDATION:

Non-occupational PEP should be offered as soon as possible after exposure and initiated ideally within 2 hours and no later than 36 hours following exposure. Non-occupational PEP is unlikely to be effective more than 36 hours post-exposure.

V. RECOMMENDED nPEP REGIMENS

RECOMMENDATIONS:

Clinicians should initiate three-drug ARV therapy for significant exposures to HIV. The preferred nPEP regimen is zidovudine 300 mg po bid + lamivudine 150 mg po bid (or co-formulated as Combivir 1 bid) plus tenofovir 300 mg po qd. Alternative agents may be used in the setting of drug intolerance or toxicity (see Table 5 and Appendix A).

When the patient is known to be HIV infected and information regarding previous ARV therapy, current level of viral suppression, or genotypic/phenotypic resistance profile is available, the clinician, in consultation with an HIV Specialist, should individualize the regimen to more effectively suppress viral replication.

The nPEP regimen should be continued for 4 weeks.

TABLE 5
HIV PEP REGIMEN FOLLOWING NON-OCCUPATIONAL EXPOSURE*†

Zidovudine‡ 300 mg po bid + Lamivudine 150 mg po bid
(or Combivir 1 bid)§

Plus

Tenofovir 300 mg po qd¶

Notes:

* When the source is known to be HIV infected, past and current ARV therapy experience, viral load data, and genotypic or phenotypic resistance data (if available) may indicate the use of an alternative PEP regimen. Consult an HIV Specialist.

† **NNRTIs should be considered only when 1) the patient cannot tolerate either tenofovir or a protease inhibitor alternative, or 2) the patient has been exposed to a source with known drug-resistant HIV that is sensitive to NNRTIs.** Use of efavirenz should only be considered in men and in women not capable of bearing children because of associations with teratogenicity in animal studies and in anecdotal reports in humans. Initial central nervous system toxicity, often seen with efavirenz, may affect one's ability to work. Nevirapine is not recommended for women with CD4 counts >250 cells/mm³ or men with CD4 counts >400 cells/mm³ and should only be used when NRTIs or PIs are not an option and no other hepatic risk (e.g., hepatitis) is present. If nevirapine is used, it is essential that the 14-day lead-in period be strictly followed. Serum liver enzymes should be obtained at baseline, at dose escalation, and 2 weeks after dose escalation.

‡ If the patient is intolerant to zidovudine, stavudine 40 mg po bid may be substituted (if patient is <60 kg, 30 mg po bid should be given). Dosing interval of zidovudine should be adjusted in patients with baseline creatinine clearance <15 mL/min (see Appendix A for dosing recommendations).

§ The dosing interval of lamivudine should be adjusted in patients with baseline creatinine clearance <50 mL/min (see Appendix A for dosing recommendations). Because Combivir is a fixed-dose combination that cannot be adjusted, zidovudine 300 mg twice daily should be combined with lamivudine (dose adjusted for creatinine clearance).

¶ The dosing interval of tenofovir should be adjusted in patients with baseline creatinine clearance <50 mL/min (see Appendix A for dosing recommendations).

VI. MONITORING FOLLOWING NON-OCCUPATIONAL EXPOSURE INCLUDING SEXUAL ASSAULT

RECOMMENDATIONS:

Clinicians should closely monitor people receiving nPEP to detect ARV-induced toxicities.

Because of the complexity and potential adverse effects of the nPEP regimens, longitudinal care of the exposed patient should be provided either directly by or in consultation with an HIV Specialist.

Sequential confidential HIV testing should be obtained at baseline, 1, 3, and 6 months post-exposure even if nPEP is declined (see Table 6). In New York State, if the test result is positive, a Western blot assay must be performed to confirm the diagnosis of HIV infection.

Any acute febrile illness post-exposure accompanied by one or more of the following—rash, lymphadenopathy, myalgias, sore throat—suggests the possibility of acute HIV seroconversion and requires urgent evaluation. If this constellation of complaints is encountered, consultation with an HIV Specialist should be sought for optimal diagnostic testing and treatment options.

TABLE 6 MONITORING RECOMMENDATIONS AFTER INITIATION OF PEP REGIMENS FOLLOWING NON-OCCUPATIONAL EXPOSURE				
	Clinic Visit	CBC with Differential	Serum Liver Enzymes	HIV Antibody*
Baseline	X	X	X	X
Week 1	X			
Week 2	X	X	X	
Week 3	X			
Month 1	X	X	X	X
Month 3				X
Month 6				X

*Recommended even if PEP is declined.

VII. NON-OCCUPATIONAL PEP FOR THE PREGNANT PATIENT

RECOMMENDATIONS:

Before administering nPEP to a pregnant woman, the clinician should discuss the potential benefits and risks to her and to the fetus. Drugs to avoid during pregnancy are listed in Table 7.

Based on increasing clinical experience with HAART, nPEP is indicated at any time during pregnancy when a significant exposure has occurred, despite possible risk to the woman and the fetus. Expert consultation should be sought. A decision about the initiation of nPEP should be made within 36 hours of exposure, which is the period for optimal prophylaxis.

Clinicians should not prescribe efavirenz for pregnant women because it has been associated with teratogenicity in monkeys.

Clinicians should not prescribe amprenavir in the second and third trimesters because it may induce fetal skeletal ossification.

Clinicians should not prescribe the combination of didanosine and stavudine due to an increased risk of mitochondrial toxicity in pregnant women.

For women who may have been exposed to HIV, breastfeeding should be avoided for 6 months after the exposure. Because HIV infection is most often diagnosed within 3 months of exposure, women who would prefer to breastfeed between 3 to 6 months following exposure should carefully discuss the risks and benefits with the clinician.

TABLE 7 PEP DRUGS TO AVOID DURING PREGNANCY	
Drug(s) to Avoid	Toxicity
Efavirenz	Teratogenicity
Amprenavir in the second or third trimester	Fetal skeletal ossification
Combination of stavudine and didanosine	Mitochondrial toxicity

VIII. NON-OCCUPATIONAL PEP FOR HEPATITIS B AND C

RECOMMENDATIONS:

The hepatitis B vaccine series should be initiated in non-HBV-immune patients who sustain a blood or body fluid exposure.

Administration of prophylactic hepatitis B immune globulin (HBIG) and the initiation of the hepatitis B vaccine series are recommended when the non-HBV-immune patient is exposed to a source with acute or chronic HBV (see Table 8).

If the source is known to be HCV-antibody positive or if the serostatus is unknown, baseline HCV serology and serum alanine aminotransferase (ALT) should be obtained from the exposed patient and should be repeated at 4 to 6 months post-exposure.

If the source is known to be HCV-antibody positive, an HCV antibody and qualitative HCV viral load (HCV RNA PCR) should be obtained from the exposed patient 4 weeks after exposure.

In the setting of an acute elevation of ALT in the exposed patient in the first 24 weeks post-exposure, a qualitative HCV RNA PCR should be obtained.

When HCV infection is identified, the exposed patient should be referred for medical management to a clinician with experience in treating HCV.

IX. RESOURCES FOR CONSULTATION

Persons who have responsibility for providing nPEP may need expert advice and consultation as well as assistance in helping their clients obtain medication.

For providers in New York State, the following resources are the preferred initial contacts for expert consultation:

- The HIV Clinical Education Centers are the preferred initial contacts for expert consultation about PEP in New York State (see Appendix II: *Resources for Clinical Consultation*).
- The AIDS Institute is a secondary resource for consultation and referrals. The Institute (212-268-6142) is open between 8:30 AM and 5:00 PM. At other hours, an NYSDOH operator at 518-465-9720 will connect the caller with the Department of Health Duty Officer who can refer the caller to an appropriate resource in his/her geographic area.

For providers outside of New York State, the following resources are available:

- HIV PEP at 1-888-448-4911
- Non-Occupational PEP Registry at 1-877-448-1737
- The National Clinicians' Consultation Center PEP line at 1-888-HIV-4911

For information about rape crisis services, see Appendix B for a list of rape crisis centers and hotlines by county.

TABLE 8
RECOMMENDED POST-EXPOSURE PROPHYLAXIS FOR
NON-OCCUPATIONAL EXPOSURE TO HEPATITIS B VIRUS

Vaccination and/or antibody status of exposed patient*	Treatment when source is:		
	HBsAg positive	HBsAg negative	Source unknown or not available for testing
Unvaccinated/non-immune	HBIG† ×1; initiate HB vaccine series	Initiate HB vaccine series	Initiate HB vaccine series
Previously vaccinated, known responder‡	No treatment	No treatment	No treatment
Previously vaccinated, known non-responder‡	HBIG† ×2 or HBIG† ×1 and initiate revaccination§	No treatment	If known high-risk source, treat as if source were HBsAg positive
Previously vaccinated, anti-body response unknown	Test exposed person for anti-HBs: <ul style="list-style-type: none"> • If adequate‡, no treatment • If inadequate‡, HBIG ×1 and vaccine booster 	No treatment	Test exposed person for anti-HBs <ul style="list-style-type: none"> • If adequate‡, no treatment • If inadequate‡, initiate revaccination

Reprinted from the Updated US Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Post-Exposure Prophylaxis. *MMWR Morb Mortal Wkly Rep* 2001;50(RR-11):1-42. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm>.

HBsAg, hepatitis B surface antigen; HBIG, hepatitis B immune globulin; anti-HBs, antibody to hepatitis B surface antigen.

*Persons who have previously been infected with HBV are immune to re-infection and do not require PEP.

† Dose 0.06 mL/kg intramuscularly.

‡ Responder is defined as person with adequate levels of serum antibody to HBsAg (serum anti-HBs ≥10mIU/mL); non-responder is a person with inadequate response to vaccination (serum anti HBs <10mIU/mL).

§ The option of giving one dose HBIG and re-initiating the vaccine series is preferred for non-responders who have not completed a second 3-dose vaccine series. For persons who previously completed a second vaccine series but failed to respond, two doses of HBIG are preferred.

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APPENDIX A

ANTIRETROVIRAL DRUGS

Antiretroviral regimens used for prophylaxis for non-occupational exposure to HIV should include zidovudine, lamivudine, and tenofovir. The tables that follow include antiretroviral agents recommended for PEP as well as alternative antiretroviral drugs because the recommended regimen may require alteration based on factors such as prior use of antiretroviral therapy in the person who is the source of the exposure. For information on all antiretroviral medications, see Chapter 4A: *Antiretroviral Therapy* (available at www.hivguidelines.org).

The following tables indicate dosage, toxicity, and dose adjustment recommendations for a month-long course of prophylaxis. Because there are toxicity and dose adjustment considerations for all of these medications when used for chronic treatment, other references should also be consulted.

RECOMMENDED PEP MEDICATION: ZIDOVUDINE (ZDV)							
Trade Name	Retrovir						
Classification	Nucleoside Reverse Transcriptase Inhibitor						
Form	100-mg capsules, 300-mg tablets, 10-mg/mL IV solution, 10-mg/mL oral solution Each Combivir tablet contains ZDV 300 mg and 3TC 150 mg Each Trizivir tablet contains ZDV 300 mg, 3TC 150 mg, and ABC 300 mg						
Dosing Recommendations	200 mg tid or 300 mg bid or with 3TC as Combivir,* 1 bid or with ABC and 3TC as Trizivir,* 1 bid						
Renal Impairment Dosing	<table border="0"> <thead> <tr> <th style="text-align: left;"><u>CrCl (mL/min)</u></th> <th style="text-align: left;"><u>Dose</u></th> </tr> </thead> <tbody> <tr> <td><15</td> <td>100 mg q6-8h (or 300 mg qd)</td> </tr> <tr> <td>Hemodialysis</td> <td>100 mg q6-8h (or 300 mg qd)</td> </tr> </tbody> </table>	<u>CrCl (mL/min)</u>	<u>Dose</u>	<15	100 mg q6-8h (or 300 mg qd)	Hemodialysis	100 mg q6-8h (or 300 mg qd)
<u>CrCl (mL/min)</u>	<u>Dose</u>						
<15	100 mg q6-8h (or 300 mg qd)						
Hemodialysis	100 mg q6-8h (or 300 mg qd)						
Food Effect	Absorption similar with or without food. Fatty food may decrease bioavailability (clinical significance unknown).						
Oral Bioavailability	60%						
Serum Half-life	1.1 hour						
Intracellular Half-life	3 hours						
Route of Metabolism	Metabolized to AZT glucuronide (GAZT); renal excretion of GAZT						
Adverse Events	GI intolerance, headache, insomnia, asthenia, lipoatrophy Bone marrow suppression: anemia, neutropenia, and, less commonly, thrombocytopenia Lactic acidosis with hepatic steatosis is a rare but potentially life-threatening toxicity						
FDA Pregnancy Category	C (no maternal toxicity or fetal defects noted with long-term follow-up)						
Long-Term Animal Carcinogenicity Studies	Positive (rodent, non-invasive vaginal epithelial tumors)						
Animal Teratogen Studies	Negative (mice and rabbits)						
Black Box Warnings	Zidovudine may be associated with hematologic toxicities, including granulocytopenia and severe anemia, particularly in advanced HIV-infected patients. Prolonged zidovudine use has been associated with symptomatic myopathy. Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of antiretroviral nucleoside analogues alone or in combination.						
Drugs to Avoid	As part of the ARV regimen: Stavudine Zalcitabine Doxorubicin (additive bone marrow suppression)						
Cautious Use or Dose Adjustment							
Antivirals	Ganciclovir: Additive bone marrow suppression Ribavirin: Additive anemia – May require use of EPO						

* Combivir and Trizivir should not be used in patients with renal insufficiency. Separate components and dose based on glomerular filtration rate (GFR).

RECOMMENDED PEP MEDICATION: LAMIVUDINE (3TC)													
Trade Name	Epivir												
Classification	Nucleoside Reverse Transcriptase Inhibitor												
Form	150-, 300-mg tablets; 10-mg/mL oral solution Each Combivir tablet contains ZDV 300 mg and 3TC 150 mg Each Trizivir tablet contains ZDV 300 mg, 3TC 150 mg, and ABC 300 mg												
Dosing Recommendations	150 mg bid or 300 mg qd <50 kg: 2 mg/kg bid or with ZDV as Combivir,* 1 bid or with ZDV and ABC as Trizivir,* 1 bid												
Renal Impairment Dosing	<table border="1"> <thead> <tr> <th>CrCl (mL/min)</th> <th>Dose</th> </tr> </thead> <tbody> <tr> <td>30-49</td> <td>150 mg qd</td> </tr> <tr> <td>15-29</td> <td>150 mg first dose, then 100 mg qd</td> </tr> <tr> <td>5-14</td> <td>150 mg first dose, then 50 mg qd</td> </tr> <tr> <td><5</td> <td>50 mg first dose, then 25 mg qd</td> </tr> <tr> <td>Hemodialysis</td> <td>No data</td> </tr> </tbody> </table>	CrCl (mL/min)	Dose	30-49	150 mg qd	15-29	150 mg first dose, then 100 mg qd	5-14	150 mg first dose, then 50 mg qd	<5	50 mg first dose, then 25 mg qd	Hemodialysis	No data
CrCl (mL/min)	Dose												
30-49	150 mg qd												
15-29	150 mg first dose, then 100 mg qd												
5-14	150 mg first dose, then 50 mg qd												
<5	50 mg first dose, then 25 mg qd												
Hemodialysis	No data												
Food Effect	No food effect												
Oral Bioavailability	86%												
Serum Half-life	5-7 hours												
Intracellular Half-life	18 hours												
Elimination	Renal excretion												
Adverse Events	Minimal toxicity for adults Lactic acidosis with hepatic steatosis is a rare but potentially life-threatening toxicity												
FDA Pregnancy Category	C												
Long-Term Animal Carcinogenicity Studies	Negative (no tumors, lifetime rodent study)												
Animal Teratogen Studies	Negative												
Black Box Warnings	Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of antiretroviral nucleoside analogues alone or in combination. Epivir tablets and oral solution (used to treat HIV infection) contain a higher dose of lamivudine than Epivir-HBV tablets and oral solution (used to treat chronic hepatitis B). Patients with HIV infection should receive only doses and formulations appropriate for treatment of HIV infection.												
Drugs to Avoid	As part of the ARV regimen: Abacavir + tenofovir Emtricitabine Tenofovir + didanosine Zalcitabine												

* Combivir and Trizivir should not be used in patients with renal insufficiency. Separate components and dose based on glomerular filtration rate (GFR).

RECOMMENDED PEP MEDICATION: TENOFIVIR (TDF)									
Trade Name	Viread								
Classification	Nucleotide Reverse Transcriptase Inhibitor								
Form	300-mg tablets								
Dosing Recommendations	300 mg qd								
Renal Impairment Dosing	<table border="1"> <thead> <tr> <th>CrCl (mL/min)</th> <th>Dose</th> </tr> </thead> <tbody> <tr> <td>30-49</td> <td>300 mg q48h</td> </tr> <tr> <td>10-29</td> <td>300 mg biw</td> </tr> <tr> <td>ESRD</td> <td>300 mg q wk</td> </tr> </tbody> </table>	CrCl (mL/min)	Dose	30-49	300 mg q48h	10-29	300 mg biw	ESRD	300 mg q wk
CrCl (mL/min)	Dose								
30-49	300 mg q48h								
10-29	300 mg biw								
ESRD	300 mg q wk								
Food Effect	<p>Fatty meal ↑ TDF AUC 40% (clinical significance unknown). May take TDF with or without meals.</p> <p>Co-administration of TDF + ddi buffered tablets should be on an empty stomach TDF + ddi EC may be taken on an empty stomach or with a light meal</p>								
Oral Bioavailability	25% in fasting state; 39% with high fat meal								
Serum Half-life	17 hours								
Intracellular Half-life	10 to 50 hours								
Elimination	Renal excretion								
Adverse Events	<p>Asthenia, headache, diarrhea, nausea, vomiting, flatulence</p> <p>Although there have been no cases of lactic acidosis reported with TDF use, lactic acidosis with hepatic steatosis is a rare but potentially life-threatening toxicity with the use of NRTIs</p> <p>Rare reports of renal insufficiency</p>								
FDA Pregnancy Category	B (one study showed normal growth; however, there was a decrease in fetal bone porosity and insulin-like growth factor was observed)								
Long-Term Animal Carcinogenicity Studies	Negative (rats); in female mice, liver adenomas were increased at exposures 16 times that in humans								
Animal Teratogen Studies	Negative (osteomalacia when given to juvenile animals at high doses)								
Black Box Warnings	<p>Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs alone or in combination with other antiretrovirals.</p> <p>Viread has <i>in vitro</i> activity against HBV but is not indicated for the treatment of chronic hepatitis B virus (HBV) infection and the safety and efficacy of Viread have not been established in patients co-infected with HBV and HIV. Severe acute exacerbations of hepatitis B have been reported in patients who are co-infected with HBV and HIV and have discontinued Viread. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who discontinue Viread and are co-infected with HIV and HBV. If appropriate, initiation of anti-hepatitis B therapy may be warranted.</p>								
Drugs to Avoid	<p>As part of the ARV regimen: Atazanavir without ritonavir Lamivudine + abacavir Lamivudine + didanosine</p>								
Cautious Use or Dose Adjustment									
Antiretrovirals	<p>Atazanavir + ritonavir: ATV AUC ↓ 25%, Cmin ↓ 23% – Use ATV 300 mg + RTV 100 mg qd</p> <p>Didanosine: ddi AUC ↑ 44%, Cmax ↑ 28% – Monitor for ddi-associated toxicities; for patients ≥60 kg, ↓ ddi EC dose to 250 mg qd; for patients <60 kg ↓ ddi EC to 200 mg qd</p> <p>Lopinavir/ritonavir: LPV/r ↑ TDF – Monitor for TDF-associated adverse events</p>								
Antivirals	Cidofovir, ganciclovir, valganciclovir: May increase serum concentration of these drugs and/or TDF – Monitor for dose-related toxicities								

ALTERNATIVE PEP MEDICATION: STAVUDINE (d4T)																	
Trade Name	Zerit																
Classification	Nucleoside Reverse Transcriptase Inhibitor																
Form	15-, 20-, 30-, 40-mg capsules; 1 mg/mL for oral solution																
Dosing Recommendations	≥60 kg: 40 mg bid <60 kg: 30 mg bid																
Renal Impairment Dosing	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;"><u>CrCl (mL/min)</u></th> <th style="text-align: left;"><u>Weight</u></th> <th style="text-align: left;"><u>Dose</u></th> </tr> </thead> <tbody> <tr> <td rowspan="2">26-50</td> <td><60 kg</td> <td>15 mg q12h</td> </tr> <tr> <td>≥60 kg</td> <td>20 mg q12h</td> </tr> <tr> <td rowspan="2">10-25</td> <td><60 kg</td> <td>15 mg q24h</td> </tr> <tr> <td>≥60 kg</td> <td>20 mg q24h</td> </tr> <tr> <td>Hemodialysis</td> <td colspan="2">Same dose as CrCl 10-25 mL/min; dose after dialysis on day of dialysis</td> </tr> </tbody> </table>	<u>CrCl (mL/min)</u>	<u>Weight</u>	<u>Dose</u>	26-50	<60 kg	15 mg q12h	≥60 kg	20 mg q12h	10-25	<60 kg	15 mg q24h	≥60 kg	20 mg q24h	Hemodialysis	Same dose as CrCl 10-25 mL/min; dose after dialysis on day of dialysis	
<u>CrCl (mL/min)</u>	<u>Weight</u>	<u>Dose</u>															
26-50	<60 kg	15 mg q12h															
	≥60 kg	20 mg q12h															
10-25	<60 kg	15 mg q24h															
	≥60 kg	20 mg q24h															
Hemodialysis	Same dose as CrCl 10-25 mL/min; dose after dialysis on day of dialysis																
Food Effect	No food effect																
Oral Bioavailability	86%																
Serum Half-life	1.0 hour																
Intracellular Half-life	3.5 hours																
Elimination	Renal excretion 50%																
Adverse Events	Peripheral neuropathy (most common), pancreatitis, lipodystrophy, rapidly progressive ascending neuromuscular weakness (rare) Lactic acidosis with hepatic steatosis is a rare but potentially life-threatening toxicity																
FDA Pregnancy Category	C (may be at increased risk of lactic acidosis)																
Long-Term Animal Carcinogenicity Studies	Not completed																
Animal Teratogen Studies	Negative (but sternal bone calcium decreases in rodents)																
Black Box Warnings	<p>Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of antiretroviral nucleoside analogues alone or in combination.</p> <p>Fatal lactic acidosis has been reported in pregnant women who received a combination of stavudine and didanosine with other ARV combinations. Stavudine and didanosine combination should only be used during pregnancy if the potential benefit clearly outweighs the potential risks.</p> <p>Fatal and non-fatal pancreatitis have occurred when stavudine was part of a combination regimen with didanosine with or without hydroxyurea.</p>																
Drugs to Avoid	As part of the ARV regimen: Zalcitabine Zidovudine																
Cautious Use or Dose Adjustment																	
Antiretrovirals	Didanosine: Peripheral neuropathy, lactic acidosis, and pancreatitis have been reported with this combination – Use only if benefits clearly outweigh risks																

ALTERNATIVE PEP MEDICATION: EFAVIRENZ (EFV)	
Trade Name	Sustiva
Classification	Non-nucleoside Reverse Transcriptase Inhibitor
Form	50-, 100-, 200-mg capsules; 600-mg tablets
Dosing Recommendations	600 mg qd, preferably at bedtime on an empty stomach
Hepatic Impairment Dosing	Use with caution in patients with hepatic impairment
Food Effect	Take on an empty stomach. Avoid meals with >40-60 g fat. Fatty meal ↑ EFV AUC 28%.
Oral Bioavailability	Data not available
Serum Half-life	40-55 hours
Elimination	Metabolized by cytochrome P450 (3A4 mixed inducer/inhibitor); 14%-34% excreted in urine (glucuronidated metabolites, <1% unchanged), 16%-61% in feces
Adverse Events	Rash,* central nervous system symptoms (dizziness, somnolence, insomnia, abnormal dreams, confusion, impaired concentration, amnesia, agitation, depersonalization, hallucinations, and euphoria)† Increased transaminase levels False-positive cannabinoid test
FDA Pregnancy Category	C (avoid in pregnancy, teratogenic in monkey study)
Long-Term Animal Carcinogenicity Studies	Not completed
Animal Teratogen Studies	Positive (cynomolgus monkey-anencephaly, anophthalmia, microphthalmia)
Black Box Warnings	None

* In clinical trials, EFV was discontinued because of rash in 1.7% of patients. Rare cases of Stevens-Johnson syndrome have been reported.

† The overall frequency of any of these symptoms associated with use of efavirenz was 52% compared with 26% in controls; 2.6% of those on efavirenz discontinued the drug because of these symptoms; symptoms usually subside spontaneously after 2-4 weeks.

ALTERNATIVE PEP MEDICATION: EFAVIRENZ (EFV)	
Drugs to Avoid	As part of the ARV regimen: Fosamprenavir without ritonavir Astemizole, cisapride, ergotamine derivatives, garlic supplements, midazolam,‡ rifapentine, St. John's Wort, terfenadine, triazolam, voriconazole
Cautious Use or Dose Adjustment	
Antiretrovirals	Amprenavir: APV AUC ↓36% – Use standard APV dose + RTV 200 mg, or APV 600 mg + RTV 100 mg bid Atazanavir: ATV AUC ↓74% – Use ATV 300 mg + RTV 100 mg qd with food Fosamprenavir: f-APV C _{min} ↓36% when dosed at f-APV 1400 mg + RTV 200 mg qd – Use f-APV 700 mg + RTV 100 mg bid, or f-APV 1400 mg + RTV 300 mg qd Indinavir: IDV ↓31% – ↑IDV dose to 1000 mg q8h, or consider IDV 800 mg + RTV 200 mg q12h Lopinavir/ritonavir: LPV AUC ↓40% – ↑LPV/r dose to 533/133 mg (4 caps or 6.5 mL) bid with food Saquinavir: SQV ↓62%; EFV ↓12% – Use SQV-sgc 400 mg + RTV 400 mg q12h
Anticoagulants	Warfarin: Potential ↑ or ↓ warfarin levels – Monitor warfarin levels
Anticonvulsants	Carbamazepine, phenobarbital, phenytoin: Unknown – Use with caution; monitor anticonvulsant levels
Antimycobacterials	Clarithromycin: CL ↓39% – Monitor for efficacy; or, if possible, use alternative agent Rifabutin: RFB ↓35% – ↑RFB dose to 450-600 mg qd or 600 mg 3x/wk Rifampin: EFV ↓22% – Consider ↑EFV dose to 800 mg qd
Oral Contraceptives	Ethinyl estradiol: ↑37% – Use alternative or additional method of contraception
Selective Serotonin Reuptake Inhibitors	Sertraline: ↓sertraline – Sertraline dose adjustment should be guided by clinical response
Synthetic Narcotics	Methadone: ↓methadone levels significantly – Monitor and titrate dose to effect

‡ Can be used with caution as a single dose in a monitored situation for procedural sedation.

ALTERNATIVE PEP MEDICATION: NEVIRAPINE (NVP)	
Trade Name	Viramune
Classification	Non-nucleoside Reverse Transcriptase Inhibitor
Form	200-mg tablets; 50 mg/5 mL oral suspension
Dosing Recommendations	200 mg qd x 14 days, then 200 mg bid with or without food
Hepatic Impairment Dosing	Should not be administered in patients with moderate to severe hepatic impairment
Food Effect	No food effect
Oral Bioavailability	>90%
Serum Half-life	25-30 hours
Elimination	Metabolized by cytochrome P450 (3A4 inducer); 80% excreted in urine (glucuronidated metabolites, <5% unchanged), 10% in feces
Adverse Events	Rash,* fever, nausea, headache Increased transaminase levels, symptomatic hepatitis, including hepatic necrosis
FDA Pregnancy Category	C (no fetal defect was found in HIVNET 006 trial)
Long-Term Animal Carcinogenicity Studies	Not completed
Animal Teratogen Studies	Negative
Black Box Warnings	<p>Severe, life-threatening, and in some cases fatal hepatotoxicity, including fulminant and cholestatic hepatitis, hepatic necrosis and hepatic failure, has been reported in patients treated with nevirapine. In some cases, patients presented with non-specific prodromal signs or symptoms of hepatitis and progressed to hepatic failure. These events are often associated with rash. Women and patients with higher CD4 counts are at increased risk of these hepatic events. Women with CD4 counts >250 cells/mm³, including pregnant women receiving chronic treatment for HIV infection, are at considerably higher risk for these events. Patients with signs or symptoms of hepatitis must discontinue nevirapine and seek medical evaluation immediately.</p> <p>Severe, life-threatening skin reactions, including fatal cases, have occurred in patients treated with nevirapine. These have included cases of Stevens-Johnson syndrome, toxic epidermal necrolysis, and hypersensitivity reactions characterized by rash, constitutional findings, and organ dysfunction. Patients developing signs or symptoms of severe skin reactions or hypersensitivity reactions must discontinue nevirapine and seek medical evaluation immediately.</p> <p>It is essential that patients be monitored intensively during the first 18 weeks of therapy with nevirapine to detect potentially life-threatening hepatotoxicity or skin reactions. The greatest risk of severe rash or hepatic events (often associated with rash) occurs in the first 6 weeks of therapy. However, the risk of any hepatic event, with or without rash, continues past this period, and monitoring should continue at frequent intervals. In some cases, hepatic injury has progressed despite discontinuation of treatment.</p> <p>Nevirapine should not be restarted following severe hepatic, skin or hypersensitivity reactions. In addition, the 14-day lead-in period with nevirapine 200 mg daily dosing must be strictly followed.</p>

* In clinical trials, NVP was discontinued because of rash in 7% of patients. Rare cases of Stevens-Johnson syndrome have been reported.

ALTERNATIVE PEP MEDICATION: NEVIRAPINE (NVP)	
Drugs to Avoid	Garlic supplements, ketoconazole, rifampin, rifapentine, St. John's Wort
Cautious Use or Dose Adjustment	
Antiretrovirals	<p>Atazanavir: No data – Consider using ATV 300 mg/RTV 100 mg qd</p> <p>Indinavir: IDV ↓ 28% – ↑ IDV dose to 1000 mg q8h, or consider IDV 800 mg + RTV 100 mg bid</p> <p>Lopinavir/ritonavir: LPV Cmin ↓ 55% – ↑ LPV/r dose to 533/133 mg (4 caps or 6.5 mL) bid with food</p> <p>Saquinavir: SQV ↓ 25% – SQV-sgc 400 mg + RTV 400 mg or SQV-sgc 1000 mg + RTV 100 mg bid, or SQV-hgc 1000 mg + RTV 100 mg bid</p>
Anticonvulsants	Carbamazepine, phenobarbital, phenytoin: Unknown – Use with caution; monitor anticonvulsant levels
Antifungals	<p>Fluconazole: ↑ NVP – Monitor for NVP-associated side effects</p> <p>Voriconazole: Potential for bi-directional inhibition; may significantly ↓ voriconazole – Monitor frequently for toxicities</p>
Antimycobacterials	Clarithromycin: NVP ↑ 26%; CL ↓ 31% – Monitor for efficacy or use alternative agent
Oral Contraceptives	<p>Ethinyl estradiol: ↓ ~20% – Use alternative or additional method of contraception</p> <p>Norethindrone: ↓ norethindrone – Use alternative or additional method of contraception</p>
Synthetic Narcotics	Methadone: ↓ methadone levels significantly – Monitor and titrate dose to effect

ALTERNATIVE PEP MEDICATION: INDINAVIR (IDV)	
Trade Name	Crixivan
Classification	Protease inhibitor
Form	100-, 200-, 333-, 400-mg capsules
Dosing Recommendations	800 mg q8h or IDV 800/RTV 100 mg bid or IDV 400/RTV 400 mg bid
Hepatic Impairment Dosing	Mild to moderate hepatic impairment due to cirrhosis: 600 mg q8h
Food Effect	Unboosted: Take on empty stomach 1 hour before or 2 hours after meals; food ↓ AUC 77%. May take with skim milk or low-fat meal. Drink plenty of fluids (8-10 cups/day). Grapefruit juice ↓ IDV AUC 26%*; 1 g/day of Vitamin C ↓ IDV AUC 14%, ↓ C _{min} 32% Boosted: No food effect
Oral Bioavailability	65% (on empty stomach)
Serum Half-life	1.5–2 hours
Route of Metabolism	P450 cytochrome 3A4 inhibitor and substrate
Storage	Room temperature
Adverse Events	GI intolerance, nausea, headache, asthenia, blurred vision, dizziness, rash, metallic taste, alopecia, paronychia Nephrolithiasis, hyperglycemia, † fat redistribution and lipid abnormalities, ‡ thrombocytopenia, hemolytic anemia, possible increased bleeding episodes in patients with hemophilia, increased indirect bilirubinemia (inconsequential)
FDA Pregnancy Category	C (potential ↑ bilirubin and nephrolithiasis in neonates)
Long-Term Animal Carcinogenicity Studies	Not completed
Animal Teratogen Studies	Negative (but extra ribs in rodents)
Black Box Warnings	None

* Contrary to package insert, one study found no effect on IDV pharmacokinetics when given with orange juice or grapefruit juice (Penzak SR, et al. *J Clin Pharmacol* 2002;42:1165).

† Cases of worsening glycemic control in patients with pre-existing diabetes, and cases of new-onset diabetes including diabetic ketoacidosis have been reported with the use of all protease inhibitors.

‡ Discontinuation of PIs may be required to reverse fat redistribution. Patients with hypertriglyceridemia or hypercholesterolemia should be evaluated for risks for cardiovascular events and pancreatitis.

ALTERNATIVE PEP MEDICATION: INDINAVIR (IDV)	
Drugs to Avoid	As part of the ARV regimen: Atazanavir (potential for additive increased indirect bilirubin) Alprazolam, astemizole, cisapride, ergotamine derivatives, garlic supplements, lovastatin, midazolam,§ pimoziide, rifampin, rifapentine, simvastatin, St. John's Wort, terfenadine, triazolam
Cautious Use or Dose Adjustment	
Antiretrovirals	Delavirdine: ↑IDV – ↓IDV dose to 600 mg q8h Didanosine: IDV AUC ↓84% – Take IDV 1 hour before or after buffered ddi on an empty stomach (no interaction with ddi EC) Efavirenz: IDV ↓31% – ↑IDV dose to 1000 mg q8h, or consider IDV 800 mg + RTV 200 mg q12h Lopinavir/ritonavir: ↑IDV – ↓IDV dose to 600 mg bid or 666 mg bid Nelfinavir: IDV ↑50%; NFV ↑80% – Consider IDV 1200 mg + NFV 1250 mg bid (limited data) Nevirapine: IDV ↓28% – ↑IDV dose to 1000 mg q8h, or consider IDV + RTV Ritonavir: IDV ↑2- to 5-fold – Use IDV 400 mg + RTV 400 mg bid or IDV 800 mg + RTV 100 mg bid; renal events may be increased with higher IDV Cmax
Anticonvulsants	Carbamazepine: Markedly ↓IDV – Consider phenytoin, phenobarbitol, valproic acid, levetiracetam, or topiramate
Antidepressants	Trazodone: May lead to substantial ↑ in trazodone – Consider ↓ dose of trazodone
Antifungals	Itraconazole: ↓unboosted IDV dose to 600 mg tid – Do not exceed 200 mg itraconazole bid Ketoconazole: IDV ↑68% – ↓IDV dose to 600 mg tid Voriconazole: When IDV is boosted with RTV, potential for bi-directional inhibition – Monitor for toxicities
Antimycobacterials	Rifabutin: IDV ↓32%; RFB ↑204% – ↓RFB dose to 150 mg qd or 300 mg 3x/wk.¶ ↑IDV dose to 1000 mg q8h. If IDV is boosted with RTV, use RFB 150 mg qod + IDV 400 mg + RTV 400 mg bid.
Erectile Dysfunction Agents	Sildenafil: Sildenafil AUC ↑3-fold – Use cautiously, start with reduced dose of 25 mg q48h and monitor for adverse effects Tadalafil: Substantial ↑ in tadalafil AUC and half-life – Start with a 5-mg dose, and do not exceed a single dose of 10 mg in 72 hours Vardenafil: Vardenafil ↑16-fold; IDV (unboosted) ↓30% – For unboosted IDV, consider using sildenafil instead; for IDV + RTV, do not exceed 2.5 mg vardenafil in 72 hours
Lipid-Lowering Agents	Atorvastatin: Potential for ATO AUC ↑ – Use lowest possible starting dose of ATO with careful monitoring (consider pravastatin or rosuvastatin)

§ Can be used with caution as a single dose in a monitored situation for procedural sedation.

¶ Rifabutin 3x/wk is recommended if CD4 cell count <100 cells/mm³.

ALTERNATIVE PEP MEDICATION: LOPINAVIR/RITONAVIR (LPV/r)	
Trade Name	Kaletra
Classification	Protease inhibitor
Form	LPV 133.3 mg/RTV 33.3 mg capsules with food LPV 80 mg/RTV 20 mg per mL oral solution (contains 42% alcohol) with food
Dosing Recommendations	LPV 400 mg/RTV 100 mg (3 capsules or 5.0 mL oral solution) bid
Hepatic Impairment Dosing	Use with caution in patients with hepatic impairment
Food Effect	Take with food. To increase absorption by 50-80%, take with meal containing >15 g of fat.
Oral Bioavailability	Not determined in humans
Serum Half-life	5-6 hours
Route of Metabolism	P450 cytochrome 3A4 inhibitor and substrate
Storage	Refrigerated capsules stable until expiration date on label. If stored at room temperature, stable for 2 months.
Adverse Events	GI intolerance, nausea, vomiting, diarrhea, asthenia Elevated serum transaminase, hyperglycemia,* fat redistribution and lipid abnormalities,† possible increased bleeding episodes in patients with hemophilia
FDA Pregnancy Category	C
Long-Term Animal Carcinogenicity Studies	Not completed
Animal Teratogen Studies	Negative (but delayed skeletal ossification and increase in skeletal variations in rats at maternally toxic doses)
Black Box Warnings	None

* Cases of worsening glycemic control in patients with pre-existing diabetes, and cases of new-onset diabetes including diabetic ketoacidosis have been reported with the use of all protease inhibitors.

† Discontinuation of PIs may be required to reverse fat redistribution. Patients with hypertriglyceridemia or hypercholesterolemia should be evaluated for risks for cardiovascular events and pancreatitis.

ALTERNATIVE PEP MEDICATION: LOPINAVIR/RITONAVIR (LPV/r)	
Drugs to Avoid	As part of the ARV regimen: Amprenavir Fosamprenavir Alprazolam, astemizole, cisapride, ergotamine derivatives, flecainide, garlic supplements, lovastatin, midazolam,‡ phenytoin, pimozone, propafenone, rifampin,§ rifapentine, simvastatin, St. John's Wort, terfenadine, triazolam
Cautious Use or Dose Adjustment	
Antiretrovirals	Efavirenz: LPV AUC ↓40% – ↑LPV/r dose to 533/133 mg (4 caps or 6.5 mL) bid with food Indinavir: ↑IDV – ↓IDV dose to 600 mg bid <i>or</i> 666 mg bid Nevirapine: LPV C _{min} ↓55% – ↑LPV/r dose to 533/133 mg (4 caps or 6.5 mL) bid with food Saquinavir: SQV AUC and C _{min} ↑ – Use SQV-hgc 800-1000 mg bid
Anticonvulsants	Carbamazepine, phenobarbital: Levels ↑ when co-administered with RTV – Use with caution; monitor anticonvulsant levels
Antifungals	Itraconazole: Itraconazole ↑ – Use with caution, do not exceed 200 mg itraconazole daily Ketoconazole: LPV AUC ↓13%; keto ↑3-fold – Use with caution, do not exceed 200 mg keto daily Voriconazole: Potential for bi-directional inhibition; when boosted with RTV, may significantly ↓ voriconazole – Monitor for toxicities
Antimycobacterials	Clarithromycin: CL AUC ↑77% – Adjust CL dose for moderate and severe renal impairment Rifabutin: RFB AUC ↑3-fold; 25-O-desacetyl metabolite ↑47.5-fold – ↓RFB dose to 150 mg qod
Erectile Dysfunction Agents	Sildenafil: Sildenafil AUC ↑11-fold when co-administered with RTV – Use cautiously, start with reduced dose of 25 mg q48h, and monitor for adverse effects Tadalafil: Substantial ↑ in tadalafil AUC and half-life – Start with a 5-mg dose, and do not exceed a single 10-mg dose in 72 hours Vardenafil: May substantially ↑ vardenafil AUC – Start with a 2.5-mg dose, and do not exceed a single 2.5-mg dose in 72 hours
Lipid-Lowering Agents	Atorvastatin: ATO AUC ↑5.88-fold – Use lowest possible starting dose of ATO with careful monitoring
Oral Contraceptives	Ethinyl estradiol: EE ↓42% – Use alternative or additional method

‡ Can be used with caution as a single dose in a monitored situation for procedural sedation.

§ In one small study, an increased dose of LPV/r 800/200 mg was used to offset rifampin-inducing activity of LPV; the standard dose of rifampin was used. 28% of patients discontinued this regimen due to increases in LFTs. The safety of this combination has not been established, and if used, close monitoring, including measuring LPV concentrations, is recommended.

ALTERNATIVE PEP MEDICATION: NELFINAVIR (NFV)	
Trade Name	Viracept
Classification	Protease inhibitor
Form	250-, 625-mg tablets, 50 mg/g oral powder
Dosing Recommendations	750 mg tid or 1250 mg bid
Hepatic Impairment Dosing	Use with caution in patients with hepatic impairment
Food Effect	Levels increase 2- to 3-fold; take with meal or snack To increase absorption, take with meal containing 500-1000 kcal (20-50% fat)
Oral Bioavailability	20-80%
Serum Half-life	3.5-5 hours
Route of Metabolism	P450 cytochrome 3A4 inhibitor (less than ritonavir)
Storage	Room temperature
Adverse Events	Diarrhea (most common), hyperglycemia,* serum transaminase elevation, fat redistribution and lipid abnormalities† Possible increased bleeding episodes in patients with hemophilia
FDA Pregnancy Category	B (of 757 births reported to the Registry, the rate of birth defects was comparable to the general population)
Long-Term Animal Carcinogenicity Studies	Not completed
Animal Teratogen Studies	Negative
Black Box Warnings	None

* Cases of worsening glycemic control in patients with pre-existing diabetes, and cases of new-onset diabetes including diabetic ketoacidosis have been reported with the use of all protease inhibitors.

† Patients with hypertriglyceridemia or hypercholesterolemia should be evaluated for risks for cardiovascular events and pancreatitis.

ALTERNATIVE PEP MEDICATION: NELFINAVIR (NFV)	
Drugs to Avoid	Alprazolam, amiodarone, astemizole, cisapride, ergotamine derivatives, garlic supplements, lovastatin, midazolam,‡ pimozone, quinidine, rifampin, rifapentine, simvastatin, St. John's Wort, terfenadine, triazolam
Cautious Use or Dose Adjustment	
Antiretrovirals	Indinavir: IDV ↑50%; NFV ↑80% – Consider IDV 1200 mg bid + NFV 1250 mg bid (limited data) Ritonavir: NFV ↑1.5-fold – Consider NFV 500-750 mg + RTV 400 mg bid (limited data; only a modest benefit with RTV boosting) Saquinavir: SQV ↑3- to 5-fold; NFV ↑20% – ↓SQV- <i>sgc</i> dose to 800 mg tid or 1200 mg bid
Anticonvulsants	Carbamazepine, phenobarbital, phenytoin: May ↓NFV levels substantially – Monitor anticonvulsant levels and virologic response. Consider obtaining NFV levels (target C _{min} >0.8).
Antifungals	Voriconazole: Potential for bi-directional inhibition – Monitor for toxicities
Antimycobacterials	Azithromycin: ↑azithromycin – Monitor for adverse effects Rifabutin: NFV AUC ↓32%; RFB ↑207% – ↓RFB dose to 150 mg qd or 300 mg 3x/wk.§ ↑NFV dose to 1000 mg q8h. If NFV is boosted with RTV, use RFB 150 mg qod + NFV 500-750 mg bid + RTV 400 mg bid (limited data).
Erectile Dysfunction Agents	Sildenafil: Sildenafil AUC ↑2- to 11-fold – Use cautiously, start with reduced dose of 25 mg q48h and monitor for adverse effects Tadalafil: Substantial ↑ in tadalafil AUC and half-life – Start with a 5-mg dose; do not exceed a single 10-mg dose of tadalafil in 72 hours Vardenafil: May ↑ vardenafil AUC – Start with 2.5-mg dose; do not exceed a single 2.5-mg dose of vardenafil in 72 hours
Lipid-Lowering Agents	Atorvastatin: ATO AUC ↑74% – Use lowest possible starting dose of ATO with careful monitoring
Oral Contraceptives	Ethinyl estradiol: ↓47% – Use alternative or additional method of contraception Norethindrone: ↓18% – Use alternative or additional method of contraception
Synthetic Narcotics	Methadone: May ↓methadone levels – Monitor and titrate dose if needed. No significant change in the R-methadone (active). No withdrawal symptoms observed.

‡ Can be used with caution as a single dose in a monitored situation for procedural sedation.

§ Rifabutin 3x/wk is recommended if CD4 cell count <100 cells/mm³.

APPENDIX B

RAPE CRISIS PROGRAM

The Rape Crisis Program is the only New York State agency-sponsored program that focuses on sexual assault prevention and treatment for survivors of sexual assault. Located within the Bureau of Women's Health, the Rape Crisis Program's mission is to support activities to prevent sexual assault and to ensure that services are available, accessible, and appropriate for sexual assault survivors.

The Rape Crisis Program is committed to improving New York State's response to sexual assault survivors through advocacy, policy development, and coordination and oversight of a statewide network of rape crisis service providers. Technical assistance on sexual assault issues is provided within the NYSDOH, with other State agencies, healthcare facilities, and professional organizations.

ALBANY COUNTY

Albany County Rape Crisis Center

Albany, NY
(518) 447-5500 Office
(518) 447-7716 Hotline

New York State Coalition Against Sexual Assault

Albany, NY
(518) 482-4222 Office

ALLEGANY COUNTY

Cattaraugus Community Action, Inc.

Salamanca, NY
(716) 945-1041, Ext. 19 Office
(716) 945-3970 Hotline

BROOME COUNTY

Crime Victims Assistance Center, Inc.

Binghamton, NY
(607) 723-3200 Office
(607) 722-4256 Hotline

CATTARAUGUS COUNTY

Cattaraugus Community Action, Inc.

Salamanca, NY
(716) 945-1041, Ext. 19 Office
1-888-945-3970 Hotline

CAYUGA COUNTY

Sexual Assault Victim's Advocate Resource

Cayuga Counseling Services

Auburn, NY
(315) 253-9795 Office
(315) 252-2112 Hotline

CHAUTAUQUA COUNTY

Rape Crisis Services

The Salvation Army

Jamestown, NY
(716) 664-6567 Office
1-800-252-8748 Hotline

CHEMUNG COUNTY

Rape Crisis of the Southern Tier

Horseheads, NY
(607) 796-0220 Office
1-888-810-0093 Hotline

CHENANGO COUNTY

Crime Victim/Witness Assistance

Chenango County Catholic Charities

Norwich, NY
(607) 334-3532 Office
(607) 336-1101 Hotline

CLINTON COUNTY

Crisis Center of CEF

Plattsburgh, NY
(518) 561-2330/2331 Office
1-800-342-5767 Hotline

COLUMBIA COUNTY

The REACH Center

Hudson, NY
(518) 828-5556 Office
1-888-943-2472 Hotline

CORTLAND COUNTY

Aid to Victims of Violence Program

YWCA-Cortland

Cortland, NY
(607) 753-3639 Office
(607) 756-6363 Hotline

DELAWARE COUNTY

Delaware Opportunities, Inc.

Delhi, NY
(607) 746-2165 Office
(607) 746-6278 Hotline
1-866-457-7233 Hotline

DUTCHESS COUNTY

Family Services, Inc.

Poughkeepsie, NY
(845) 452-1110 Office
(845) 452-7272 Hotline

ERIE COUNTY

Suicide Prevention & Crisis Services, Inc.

Buffalo, NY
(716) 834-2310 Office
(716) 834-3131 Hotline

ESSEX COUNTY

Crisis Center of CEF

Elizabethtown, NY
(518) 873-6514 Office
1-800-342-5767 Hotline

FRANKLIN COUNTY

Crisis Center of CEF

Malone, NY
(518) 483-8211 Office
1-800-342-5767 Hotline

FULTON COUNTY

Rape Crisis Service

Planned Parenthood Mohawk Hudson, Inc.

Gloversville, NY
(518) 773-0040 Office
(518) 843-4367 Hotline

GENESEE COUNTY

**Rape Crisis Service of Genesee County
(PP Rochester/Syracuse Region, Inc.)**

Batavia, NY
(585) 344-0541 Office
1-800-527-1757 Hotline

GREENE COUNTY

The REACH Center

Hudson, NY
(518) 943-4482 Office
(518) 758-6696 Hotline

HAMILTON COUNTY

Planned Parenthood Mohawk Hudson, Inc.

Hamilton-PP Mohawk Hudson, Inc.

Schenectady, NY
(518) 792-4305 Office
1-866-307-4086 Hotline

YWCA of the Mohawk Valley

Hamilton-YWCA-Utica

Utica, NY
(315) 866-6738 Office
1-800-342-5767 Hotline

Crisis Center of CEF

Hamilton-CEF

(518) 873-6514 Office
1-800-342-5767 Hotline

HERKIMER COUNTY

YWCA of the Mohawk Valley

Sexual Violence Services

Herkimer, NY
(315) 866-0748 Office
(315) 866-4120 Hotline

JEFFERSON COUNTY

Victims Assistance Center of Jefferson County

Watertown, NY
(315) 782-1823 Office
(315) 782-1855 Hotline

LEWIS COUNTY

HELP Hotline

Lewis County Opportunities, Inc.

Lowville, NY
(315) 376-8202 Office
(315) 376-4357 Hotline

LIVINGSTON COUNTY

Rape Crisis Service of Livingston County

(PP Rochester/Syracuse Region, Inc.)

Dansville, NY
(585) 335-3020 Office
1-800-527-1757 Hotline

MADISON COUNTY

Victims of Violence

Liberty Resources

Oneida, NY
(315) 363-0048 Office
(315) 366-5000 Hotline

MONROE COUNTY

Rape Crisis Service

(PP of Rochester/Syracuse Region, Inc.)

Rochester, NY
(585) 546-2777 Office/Hotline

MONTGOMERY COUNTY

Rape Crisis Service

Planned Parenthood Mohawk Hudson, Inc.

Amsterdam Memorial Hospital
Amsterdam, NY
(518) 843-0945 Office
(518) 843-4367 Hotline

NASSAU COUNTY

**Center for Rape/Sexual Assault Services
Nassau County Coalition Against Domestic
Violence, Inc.**

Hampstead, NY
(516) 572-0700 Office
(516) 222-2293 Hotline

NIAGARA COUNTY

Niagara County Rape Crisis Services

Niagara Falls, NY
(716) 278-1940 Office
(716) 285-3518 Hotline

ONEIDA COUNTY

**Rape Crisis Service
YWCA-Utica**

Utica, NY
(315) 732-2159 Office
(315) 797-7740 Hotline

ONONDAGA COUNTY

Rape Crisis Center of Syracuse

Syracuse, NY
(315) 422-7273 Office/Hotline

ONTARIO COUNTY

Rape and Abuse Crisis Service of the Finger Lakes

Geneva, NY
(315) 781-1093 Office
1-800-247-7273 Hotline

ORANGE COUNTY

Mental Health Association of Orange County

Goshen, NY
(845) 294-7411 Office
1-800-832-1200 Hotline

ORLEANS COUNTY

**Rape Crisis Service of Orleans County
(PP Rochester/Syracuse Region, Inc.)**

Albion, NY
(585) 589-1312 Office
1-800-527-1757 Hotline

OSWEGO COUNTY

SAF Rape Crisis Program

Oswego, NY
(315) 342-1544 Office
(315) 342-1600 Hotline

OTSEGO COUNTY

Violence Intervention Program

Oneonta, NY
(607) 433-8038 Office
(607) 432-4855 Hotline

PUTNAM COUNTY

**Putnam-North Westchester
Women's Resource Center**

Mahopac, NY
(845) 628-9284 Office
(845) 628-2166 Hotline

RENSELAER COUNTY

Sexual Assault & Crime Victims Center

Samaritan Hospital
Troy, NY
(518) 271-3445 Office
(518) 271-3257 Hotline

ROCKLAND COUNTY

Sexual Trauma Services

Rockland Family Shelter
New City, NY
(845) 634-3391 Office
(845) 634-3344 Hotline

ST. LAWRENCE COUNTY

Citizens Against Violent Acts

Canton, NY
(315) 386-2761 Office
(315) 386-3777 Hotline

SARATOGA COUNTY

Saratoga Domestic Violence Services

Saratoga Springs, NY
(518) 583-0280 Office
(518) 587-2336 Hotline

SCHENECTADY COUNTY

**Rape Crisis Service
Planned Parenthood Mohawk Hudson, Inc.**

Schenectady, NY
(518) 374-5353 Office
(518) 346-2266 Hotline

SCHOHARIE COUNTY

**Rape Crisis/Sexual Assault Support
Planned Parenthood Mohawk Hudson, Inc.**

Cobleskill, NY
(518) 234-4844 Office
(518) 234-4949 Hotline

SCHUYLER COUNTY

**Rape Crisis of the Southern Tier
PP of the Southern Tier**

Montour Falls, NY
(607) 535-6744 Office
1-888-810-0093 Hotline

SENECA COUNTY

Rape and Abuse Crisis Services of Finger Lakes

Seneca Falls, NY
(315) 568-4200 Office
1-800-247-7273 Hotline

STEUBEN COUNTY

**Rape Crisis of the Southern Tier
Planned Parenthood of the Southern Tier**

Corning, NY
(607) 962-4686 Office
1-888-810-0093 Hotline

SUFFOLK COUNTY

Victims Information Bureau of Suffolk County, Inc.

Hauppauge, NY
(631) 360-3730 Office
(631) 360-3606 Hotline

SULLIVAN COUNTY

R.I.S.E.

Planned Parenthood of Mid-Hudson Valley, Inc.

Monticello, NY
(845) 791-5308 Office
(845) 791-9595 Hotline
1-866-791-9595 Hotline

TIOGA COUNTY

A New Hope Center

Owego, NY
(607) 687-6887 Office
(607) 687-6866 Hotline
1-800-696-7600 Hotline

TOMPKINS COUNTY

The Advocacy Center

Ithaca, NY
(607) 277-3203 Office
(607) 277-5000 Hotline

ULSTER COUNTY

Ulster County Crime Victims Assistance Program

Kingston, NY
(845) 277-3803 Office
(845) 340-3442 Hotline

WARREN COUNTY

**Warren County Sexual Assault Support
Planned Parenthood Mohawk Hudson, Inc.**

Glens Falls, NY
(518) 792-4305 Office
1-866-307-4086 Hotline

WASHINGTON COUNTY

Sexual Trauma & Recovery Services

Hudson Falls, NY
(518) 747-8849 Office
1-800-225-7114 Hotline

WAYNE COUNTY

Victim Resource Center of Finger Lakes

Newark, NY
(315) 331-1171 Office
1-800-456-1172 Hotline

WESTCHESTER COUNTY

Victims Assistance Services

Westchester Community Opportunities Program

Elmsford, NY
(914) 345-3113 Office
1-800-726-4041 Hotline

WYOMING COUNTY

Victim Services Program

Wyoming County Community Action

Perry, NY
(585) 237-2600 Office
(585) 786-3300 Hotline

YATES COUNTY

Rape & Abuse Crisis Service of the Finger Lakes

Penn Yan, NY
(315) 536-9654 Office
(315) 536-2897 Hotline

METROPOLITAN AREA

BRONX COUNTY

Child Sexual Abuse Program

Kingsbridge Heights Community Center
Bronx, NY
(718) 884-0700 Office/Hotline

Crime Victims Assistance Unit

Bronx, NY
(718) 590-2114 Office
1-800-862-2637 Hotline

SAFE HORIZON

Bronx Community Program

Bronx, NY
(718) 933-1000 Office
(212) 227-3000 Hotline

KINGS COUNTY

Church Avenue Merchants Block

Rape Crisis Program

Brooklyn, NY
(718) 282-5575 Office
1-800-310-2449 Hotline

SAFE HORIZON

Brooklyn Child Advocacy Center

Brooklyn, NY
(718) 330-5405 Office
(212) 577-7777 Hotline

**Long Island College Hospital
RC Intervention Program**

Brooklyn, NY
(718) 780-1459 Office/Hotline

SAFE HORIZON

Brooklyn Community Program

Brooklyn, NY
(718) 928-6950 Office
(212) 227-3000 Hotline

NEW YORK COUNTY

DOVE Program

New York Presbyterian Hospital
New York, NY
(212) 305-5130 Office
(212) 523-4728 Hotline

Crime Victims Treatment Center

St. Luke's Roosevelt Hospital
New York, NY
(212) 523-4727 Office
(212) 523-4728 Hotline

Rape Crisis Program

Bellevue Hospital Center
New York, NY
(212) 562-3435 Office/Hotline

NYC Alliance Against Sexual Assault

New York City Coalition
New York, NY
(212) 523-4185 Office

Rape Crisis Program

St. Vincent's Hospital & Medical Center
New York, NY
(212) 604-8068 Office

RC Intervention Program

Beth Israel Medical Center
New York, NY
(212) 420-4516 Office/Hotline

NYC Gay & Lesbian Anti-Violence Project

New York, NY
(212) 714-1184 x29 Office
(212) 714-1141 Hotline

Sexual Assault Violence Intervention Program

Mt. Sinai Medical Center
New York, NY
(212) 423-2140 x29 Office
(212) 227-3000 Hotline

**Rape Crisis Intervention and Prevention
Program**

Mt. Sinai Adolescent Health Center
New York, NY 10128
(212) 423-2981 Office
(212) 423-2833 Hotline

Crime Victims Treatment Center

St. Luke's Roosevelt Hospital
New York, NY
(212) 523-4728 Office/Hotline

QUEENS COUNTY

Wyckoff Heights Medical Center

Brooklyn, NY
(718) 963-7221 Office
(866) 992-5633 Hotline

Queens Hospital Center-SAVI

Jamaica, NY
(718) 883-3000 Office
(212) 227-3000 Hotline

SAFE HORIZON

Queens Community Program

Jamaica Heights, NY
(718) 899-1233 Office
(212) 227-3000 Hotline

RICHMOND COUNTY

SAFE HORIZON

Staten Island Community Program

Staten Island, NY
(718) 720-2591 Office
(212) 227-3000 Hotline

APPENDIX C

SEXUAL ASSAULT FORENSIC EXAMINER (SAFE) PROGRAM

The Sexual Assault Forensic Examiner (SAFE) program is a collaborative effort in which the Rape Crisis Center works with healthcare providers, law enforcement, and the prosecutor's office to provide a team approach to meet the needs of the sexual assault survivor.

There are three general objectives for sexual assault forensic examiner programs:

1. To provide the survivor of sexual violence with victim-centered, sensitive care and treatment.
2. To ensure quality evidence collection by a trained healthcare practitioner.
3. To provide expert testimony when needed.

Sexual assault forensic examiners are on-call for survivors of sexual assault. They have special education in the following areas:

- forensic interviewing techniques;
- cultural sensitivity;
- elderly, male, and child victims;
- health care of sexual assault survivors (e.g., emergency contraception, treatment for possible exposure to sexually transmitted diseases, and coordination of follow-up services); and
- forensic techniques (e.g., use of the colposcope, forensic photography, screening for the presence of "date rape drugs").

Together, with the sexual assault victim advocate, this team approach provides comprehensive and holistic health care.

To find out about the availability of sexual assault forensic examiner care in your community, contact your local Rape Crisis Center or Victims Services Agency.

For more information about sexual assault forensic examiner programs in New York State, contact:

New York State Coalition Against Sexual Assault
79 Central Avenue
Albany, New York 12206
phone (518) 434-1580
fax (518) 434-1581