

# HIV POST-EXPOSURE PROPHYLAXIS FOR CHILDREN BEYOND THE PERINATAL PERIOD

## I. INTRODUCTION

These guidelines have been developed to help medical providers identify and treat pediatric patients with potential HIV exposures. It is rare that children have exposures that place them at risk for acquiring HIV. Post-exposure prophylaxis (PEP) for a child differs from that for an adult in several important areas, including recommended medications and dosages, and legal and psychosocial issues. Guidelines for HIV PEP following occupational exposure have been developed for adults by the New York State Department of Health (NYSDOH),<sup>1</sup> and the United States Public Health Service (USPHS).<sup>2</sup> The NYSDOH has just published new guidelines on PEP following non-occupational exposures, including sexual assault in adults and adolescents.<sup>3</sup>

These guidelines are based on best-practice evidence and constitute the opinion of the NYSDOH Committee for the Care of Children and Adolescents With HIV Infection. There are no clinical trials in the pediatric age group to guide decision-making in the management of pediatric PEP for HIV, and consultation with a pediatric HIV Specialist is recommended (see Appendix I).

## II. EVIDENCE OF PROTECTION

### A. Human Studies

Limited controlled studies are available on efficacy of PEP in humans. Most data are from clinical studies on prevention of perinatal HIV transmission; however, one study involves PEP in healthcare workers.

#### 1. Pre-Exposure Prophylaxis: Clinical Studies

In 1994, the ACTG 076 study demonstrated a two-thirds reduction in perinatal HIV transmission when a three-part regimen of zidovudine (ZDV) was administered to HIV-infected pregnant women in the second and third trimesters of pregnancy and during labor, and then administered to the newborn for the first 6 weeks after birth.<sup>4</sup> This clinical trial led to a new standard of care for reducing HIV perinatal transmission in this setting.<sup>5</sup> Studies of more recent cohorts of pregnant women receiving ZDV alone, ZDV and lamivudine, or combinations including protease inhibitors or nevirapine have shown similar or even greater reductions in transmission.<sup>6-8</sup>

#### 2. Post-Exposure Prophylaxis: Clinical Studies

An observational study from New York State described a transmission rate of 5.0% when ZDV was initiated in the prenatal period, 5.3% when initiated in labor, and 9.5% when initiated within 48 hours after birth (within this subset, the transmission rate for infants who received PEP within 12 hours after birth was 5.9%, and higher for those who received prophylaxis between 12 and 48 hours). The transmission rate was 31.6% with no ZDV prophylaxis.<sup>9</sup>

A Centers for Disease Control and Prevention (CDC) retrospective case control study of HIV PEP with ZDV in healthcare workers demonstrated a 79% reduction in transmission (95% CI, 43%-94%) after percutaneous exposure to HIV.<sup>10</sup> The risk of HIV transmission was greater when the healthcare worker was exposed to a larger volume of blood.<sup>11</sup>

To date, all studies of PEP have used a single nucleoside analogue or non-nucleoside analogue. The only data that support the use of combination ARV therapy for PEP are from perinatal studies which show that lower rates of transmission occur when combination therapy is given in the antenatal period.<sup>6-8</sup>

## **B. Animal Studies**

With limited data available from humans, animal models offer one way to evaluate the efficacy of PEP. PEP regimens have been shown to be effective in preventing infection in animals. More than one dose of PEP is necessary, with most models offering 2 to 4 weeks of PEP. In these studies, PEP has been shown to be effective when initiated early after exposure; when PEP is delayed, efficacy declines. These animal studies demonstrate the efficacy of PEP and confirm the critical time-dependent nature of PEP.

PEP with intravenous ZDV (1, 8, 24, or 72 hours after exposure) was not successful in prevention of transmission of simian immunodeficiency virus (SIV) following an intravenous inoculation in macaques, although it did decrease the level of viral replication.<sup>12</sup>

PMPA, the active ingredient of the nucleotide analogue tenofovir, was protective when given to 24 macaques 4 or 24 hours after an intravenous exposure to SIV and continued for 28 days (all were protected).<sup>13</sup> When the drug was administered after 24 hours, the protection was less. Also, if treatment was continued for less than 28 days, protection was reduced.

In another study, the nucleoside analogue BEA-005 was protective in macaques when administered subcutaneously within 8 hours of intravenous exposure to SIV and continued for 3 days.<sup>14</sup> Lower doses of drug, initiation of PEP at later time points, shorter duration of PEP, and/or increase in viral inoculum resulted in diminished effect. When initiated 24 hours after inoculation, 1/2 of the macaques were protected; when initiated 3 or 6 days after inoculation, 4/4 of the macaques were not protected.

PEP with ZDV administered subcutaneously to macaques and continued for 14 days after intravenous exposure to SIV protected 1/3 of the macaques at 1 hour; none of the macaques that received the drug starting at 24 or 72 hours were protected. However, death was delayed in one animal in the group that received the drug at 24 hours.<sup>15</sup>

In the HIV/SCID-hu mouse model, ZDV PEP initiated at 30 minutes or 1, 2, 8, 24, 36, or 48 hours (and continued for 14 days) after intraperitoneal HIV challenge protected all mice in the group that received the drug within 2 hours, with time-related reduction in protection between 8 and 36 hours. No protection was demonstrated in mice that received ZDV PEP at 48 hours.<sup>16</sup>

## **III. ROUTES OF HIV TRANSMISSION**

HIV transmission may occur in the following settings:

- Exposure to blood, visibly bloody fluids, or other potentially infectious body fluid through an open wound, broken skin, or mucous membrane
- Sexual exposure
- Perinatal exposure

Infectious body fluids include blood, semen, breast milk, and vaginal secretions. Tears, saliva, and urine do not contain HIV in significant amounts or inhibit its replication and are considered non-infectious unless they contain visible blood. See Table 1 for estimated risks of transmission following different types of exposures.

Other types of contacts are not known to be associated with a risk of HIV transmission. Casual contact that occurs during childhood and household activities is not associated with an increased risk of transmission.

<b>TABLE 1</b>		
<b>ESTIMATED RISK OF HIV TRANSMISSION FOLLOWING DIFFERENT TYPES OF EXPOSURES*</b>		
<b>Type of Exposure</b>	<b>Estimated Risk</b>	<b>Reference</b>
Percutaneous exposure to infected blood (in HCWs)	0.3% (1 in 333)	Ref. 2
Mucous membrane exposure to infected blood (in HCWs)	0.09% (1 in 1100)	Ref. 2
Needle-sharing exposure to an infected source	0.67% (1 in 150)	Ref. 17
Anal intercourse with an infected source (receptive/insertive)	0.5%-3.0% (1-6 in 200)/ 0.065% (1 in 1500)	Refs. 18,19
Vaginal intercourse with an infected source (receptive/insertive)	0.1% (1 in 1000)/0.05% (1 in 2000)	Refs. 19,20
Oral sex with ejaculation with an infected source	Conflicting data—however, risk is considered to be low†	Refs. 21,22

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

† It is prudent to recommend PEP for receptive oral sex with ejaculation, although discussion about the conflicting data should occur.<sup>21,22</sup>

### **A. HIV Transmission and Casual Contact**

Findings from several large cohorts of children emphasize that HIV is not transmitted through casual contact. Rare case reports describe transmission in casual settings that are more likely related to transmission following exposure to infected blood or body fluid than to casual contact.

Two reports describe transmission of HIV from an infected child to another child in a household setting. However, in both instances, the mode of transmission was thought to be unrecognized exposure to the HIV-infected blood of the other child. The first instance involved two children between the ages of 2 and 5 years in the same household. The infected child had frequent nosebleeds, bleeding gums, and purulent otorrhea. The child who became infected had a recurrent papulovesicular excoriated rash. The children had a history of biting, sharing a bed, and sharing toothbrushes.<sup>23</sup> The second report involved two brothers with hemophilia. The older brother contracted HIV through infected cryoprecipitate or Factor VIII. Both boys received repeated infusions of Factor at home and in the hospital. The mode of transmission was thought to be through intravenous or percutaneous exposure to the older sibling's blood, although such exposure was not documented.<sup>24</sup> There are only three other reports of possible household transmission, all with presumed but undocumented blood contact.<sup>25</sup>

These cases emphasize that HIV is transmissible through exposure to infected blood or body fluid in casual settings. However, studies of several large cohorts that document no transmission through casual contact support the conclusion that HIV is not transmitted through casual contact without involvement of blood or infectious body fluids.<sup>25,26</sup>

### **B. HIV Transmission Associated With Saliva and Biting**

An estimated 250,000 human bites occur annually in the United States. Biting is a common occurrence among young children and in daycare settings. The levels of HIV detected in saliva alone are very low. Although possible, HIV transmission following bites is thought to be extremely rare. The few documented cases of possible HIV transmission following bites were in adults exposed to blood-tinged saliva.<sup>27,28</sup>

A bite wound that results in blood exposure should prompt consideration of PEP. When a human bite occurs, it is possible for both the person bitten and the biter to have incurred blood exposure. Blood exposure could occur in the following scenarios involving bites:

- *Blood exposure to the biter:* when the biter inflicts a wound that breaks the skin and blood from the bitten person enters the biter's mouth
- *Blood exposure to the bitten person:* when the biter has blood in his/her mouth (e.g., from bleeding gums or lesions) and inflicts a wound that breaks the skin of the person bitten
- *Blood exposure to both parties:* when there is a break in the skin of the bitten person and blood in the mouth of the biter

A bite is not considered a risk exposure to either party when the integrity of the skin is not disrupted.

### **C. HIV Transmission Following Sexual Exposure**

The probability of HIV transmission per episode of consensual sexual contact with an infected source is estimated to be 0.1% (1 in 1000) through vaginal intercourse and 0.5% (1 in 200) to 3.0% (1 in 33) per episode of receptive anal intercourse (see Table 1).<sup>18-21</sup> HIV transmission has been reported in the absence of ejaculation as a result of the virus being present in pre-ejaculatory fluid.

Risk of transmission at the time of sexual assault with associated trauma, bleeding, and tissue injury may be significantly higher than that observed through consensual sexual contact. Sexually transmitted diseases, as well as HIV, may be transmitted during sexual assault. No data exist regarding the frequency of HIV transmission at the time of sexual assault; however, HIV transmission has been described in children who have been sexually abused.

HIV transmission through oral sex has been described, although the per-episode risk is not well quantified. HIV transmission has occurred in orogenital sex from male to female, female to male, and male to male.

### **D. HIV Transmission Through Blood/Needle Exposure**

HIV transmission through exposure to blood in a contaminated needle is a common source of transmission among injection drug users (IDUs); however, transmission rarely occurs among healthcare workers through an accidental needlestick or among others with accidental exposure to a needle. The risk of transmission from a needlestick/blood exposure has been estimated at 95% following blood transfusion,<sup>29</sup> 0.67% per episode of exposure to a shared intravenous needle or syringe,<sup>17</sup> and 0.3% per episode of exposure to a needlestick from an HIV-infected person.<sup>30</sup> Body piercing, tattooing, and acupuncture are all potentially risky exposures if appropriate precautions for sterility of the needles are not followed.

Risk of transmission from discarded needles is thought to be a low-risk exposure. Two cohorts (59 children and 249 children) of children exposed to needlesticks from discarded needles were tested for HIV. HIV transmission did not occur in any of the children in either cohort.<sup>25</sup> HIV could not be isolated from the washings of 28 discarded needles from public places and 10 needles collected from a needle exchange program.<sup>25</sup> These studies, as well as the intolerance of HIV to environmental conditions (exposure of HIV to air over time), provide reassuring data regarding the low risk of transmission from this type of exposure.

Theoretically, the risk of transmission would be greater for an exposure to a newly discarded needle, one with a hollow bore (as opposed to a solid bore), one with visible blood, or one from an area with high HIV seroprevalence or an area frequented by IDUs.

#### IV. ASSESSMENT TO DETERMINE WHETHER PEP IS INDICATED

##### RECOMMENDATIONS:

Following an exposure, the clinician should ascertain whether the exposure is associated with a potential risk of HIV transmission (see Table 2) and whether it has occurred within the previous 36 hours.

Once the clinician has determined that a potential risk exposure has taken place, the clinician should:

- Clean the HIV-exposed wound with warm water and soap. If the mouth or eyes are involved, they should be irrigated copiously with tap water.
- Notify the parent or legal guardian unless the child/adolescent refuses parental notification and is deemed competent to make such decisions and can legally request that his/her parents not be notified.
- Refer the child to a medical facility or emergency department for immediate further evaluation of the risk of exposure and the need for PEP.
- Obtain a confidential baseline HIV antibody test.
- Assess the risk of exposure to other pathogens, including hepatitis B virus (HBV) and hepatitis C virus (HCV), tetanus, sexually transmitted diseases, and bacterial infections, and treat as necessary (see Section IX: *PEP Following Exposures to Other Infectious Agents*).

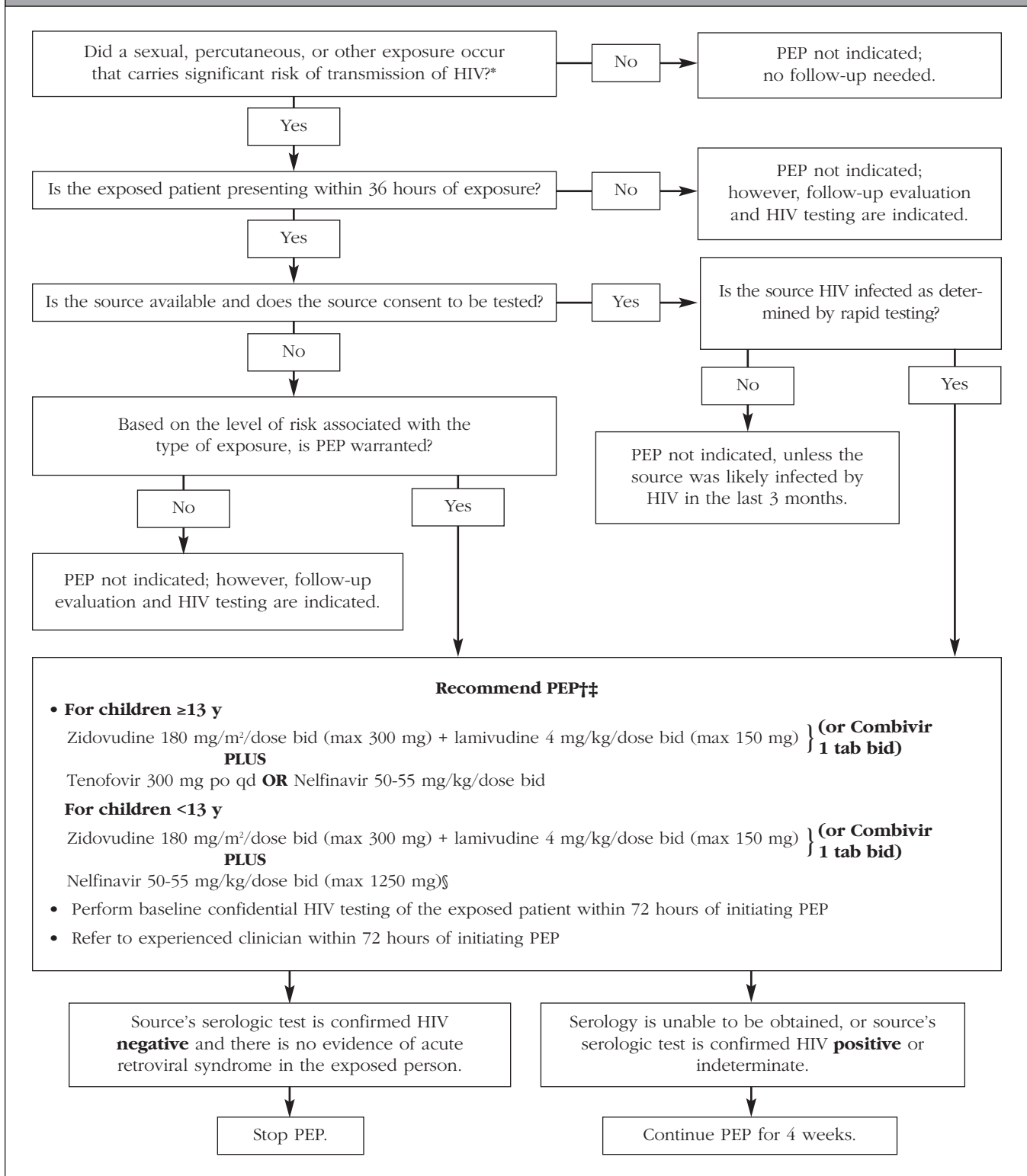
TABLE 2 CONSIDERATION OF PEP ACCORDING TO THE TYPE OF RISK EXPOSURE*	
Types of Exposures That Do Not Warrant PEP	Types of Exposures That Should Prompt Consideration of PEP
<ul style="list-style-type: none"> <li>• Kissing</li> <li>• Oral to oral contact without mucosal damage (mouth-to-mouth resuscitation)</li> <li>• Human bites not involving blood</li> <li>• Exposure to needles or sharps that have not been in contact with an HIV-infected or at-risk person</li> <li>• Oral sex without ejaculation or blood exposure</li> </ul>	<ul style="list-style-type: none"> <li>• Unprotected vaginal or anal intercourse</li> <li>• Oral sex with ejaculation or blood exposure</li> <li>• Needle sharing</li> <li>• Injuries with exposure to blood from a source known to be HIV-infected</li> <li>• Injuries with exposure to blood from a source of unknown HIV status (including needlesticks, human bites, accidents)*</li> </ul>

\* Table 1 provides risk calculations for specific exposures.

Figure 1 is a general guide that can be followed when deciding whether to initiate PEP. The following factors should be considered:

- *Type of exposure:* The probability of HIV transmission based on the description of the exposure. HIV transmission is only known to occur after exposure to blood, visibly bloody body fluid, or other infectious body fluid, including during sexual exposure (see Table 2).
- *Time since exposure:* If the exposure occurred more than 36 hours before presentation, PEP is unlikely to be beneficial in reducing transmission. The sooner PEP is initiated the better. Earlier administration of PEP in experimental animal models correlates with greater efficacy.
- *Risks and benefits of preventive therapy.*

**FIGURE 1**  
**PEP BEYOND THE PERINATAL PERIOD**



\* See Table 2.

† If a sexual assault survivor or the family of the 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 the patient to have a follow-up appointment within the next 24 hours to further discuss the indications for PEP.

‡ Consult package inserts for full dosing recommendations, drug interactions, and side effects.

§ The maximum FDA-approved dose is 1250 mg q12h. Because of the increased clearance of nelfinavir in children as compared to adults, some experts will use dosages as high as 2000 mg q12h in children who are Tanner I, II, or III.

Based on this assessment of risk, the clinician should discuss with the child/parent(s)/guardian(s) the potential risk of HIV exposure. When the risk of exposure does not warrant HIV PEP, the clinician should recommend forgoing PEP and should counsel the family accordingly. If the clinician and family feel that the risk is sufficient to warrant PEP, a careful discussion of the PEP regimen and follow-up care should take place.

When the HIV status of the source is unknown, speculation that the source is at low risk for HIV should not lessen support for a clinician's decision to initiate PEP. When the source is known to be at higher risk for HIV, this may factor into the decision to recommend HAART. Sources who may be at higher risk include those with a history of multiple sexual partners, needle-sharing behavior, or trading sex for money or drugs; men who have sex with men; and those with a sexually transmitted disease, particularly ulcerative diseases.

## **V. SPECIAL CONSIDERATIONS FOR EVALUATION OF SEXUAL ASSAULT EXPOSURES**

### **RECOMMENDATIONS:**

**Evaluation of and treatment for sexual assault should be managed by a multidisciplinary team that is experienced in the care of children or adolescents who have been sexually assaulted.**

**A Sexual Assault Forensic Examiner (SAFE) who is trained to perform pediatric examinations should be included on the team whenever possible to assist in the medical examination, coordination of care, and discussions about treatment regimen (see Appendix A). A rape crisis counselor and/or child advocacy team should be involved in all cases of sexual assault to assist the child and the family in dealing with the trauma and to assist with referrals.**

**Children and adolescents who are sexually assaulted should be managed in an emergency department or other setting where appropriate resources are available to address the medical, psychosocial, and legal issues of such an offense.**

**Children who are sexually assaulted should be assessed for the risk of acquiring other sexually transmitted diseases, including gonorrhea, syphilis, chlamydia, hepatitis B, herpes simplex virus, human papillomavirus, bacterial vaginosis, and trichomoniasis. Laboratory evaluation and possible antimicrobial prophylaxis should be considered depending on the nature of the assault.**

The multidisciplinary team should consist of medical providers with expertise in dealing with childhood sexual assault, child protective services who are mandated by law to conduct an initial assessment and investigation of reported assault/abuse, law enforcement officials to gather evidence and determine whether evidence indicates that a law has been broken, rape crisis counselors or victim advocates to provide support to the child and family, and mental health workers to provide immediate and long-term follow-up of the child and family, if appropriate (see Appendix B).

Children who present for care following sexual assault may have been the victim of multiple exposures over time. A child should be considered for PEP when the most recent exposure occurred within the preceding 36 hours. The need for HIV testing may be indicated even if exposure took place >36 hours prior to the examination.

For survivors of sexual assault, the decision to initiate PEP should not be based on the likelihood that the perpetrator is infected. Every perpetrator should be considered at risk until his/her HIV status is established. Initiation of PEP should not be delayed pending source HIV status determination.

Providers with experience in managing childhood sexual assault should assist in evaluating children/adolescents who have been sexually assaulted to best assess the comprehensive needs of the child or adolescent. PEP for HIV following sexual assault follows the same guidelines that are outlined in Section VI: *Implementing Post-Exposure Prophylaxis*.

Guidelines for the evaluation and treatment of children/adolescents who have been sexually assaulted are well detailed in the NYSDOH manual, *Child and Adolescent Sexual Offense Medical Protocol*.<sup>31</sup> The manual addresses the medical, psychosocial, and legal aspects of management of the child/adolescent following sexual assault.

Inquiries regarding child/adolescent sexual assault can be directed to Child and Adolescent Sexual Assault Medical Protocol, Rape Crisis Program, NYSDOH, ESP Corning Tower, Albany, NY 12237, or to request a copy of the protocol, call 518-474-3664.

## VI. IMPLEMENTING POST-EXPOSURE PROPHYLAXIS

### RECOMMENDATIONS:

**The clinician should discuss key issues about PEP with the family and child as soon as possible** (see Table 3).

**When parental or legal guardian consent cannot be obtained to initiate HIV PEP in a minor, the treatment may be initiated. Parental/legal guardian consent is strongly recommended to continue PEP beyond the first few hours/days. Emancipated minors, married minors, and minors who are parents may provide consent for medical care and treatment.**

**Before initiating PEP, the clinician should obtain complete blood count (CBC) and serum liver enzymes.**

**The prophylactic medication regimen should be started as soon as possible (ideally within 2 hours and not more than 36 hours following exposure) and should be continued for 28 days.**

**Medications should be made available to the patient in sufficient supply to complete a course of prophylaxis.**

**TABLE 3  
KEY ISSUES TO DISCUSS WITH FAMILY AND CHILD BEFORE INITIATING PEP**

- Potential benefits of HIV PEP
- Potential toxicities associated with medications
- Instructions on how and when to give the medications
- Importance of adherence to the medication regimen
- Nature and duration of medication regimen and monitoring schedule

Minors are defined as individuals <18 years of age. Minors may consent for or refuse HIV testing when they understand the nature and meaning of the test. Minors may also consent for emergency care if they are in need of immediate medical attention and when delay in treatment could risk their life or health. New York State Public Health law §2504 states that “medical, dental, health and hospital services may be rendered to persons of any age without the consent of a parent or legal guardian when, in the physician’s judgment, an emergency exists and the person is in immediate need of medical attention and an attempt to secure consent would result in delay of treatment, which would increase the risk to the person’s life or health.”<sup>32</sup> HIV PEP following a risky exposure may be considered an emergency situation. When parental/legal guardian consent cannot be obtained to initiate HIV PEP in a minor, the treatment may be initiated with a continuing attempt to gain parental consent, if possible.

If the patient does not have insurance and the patient is not eligible for special payment programs, the treating institution has the ethical responsibility for ensuring a timely, uninterrupted supply of medications for the patient. Sources of coverage for medications for PEP include the patient’s health insurance, the New York State Crime Victims Board, Medicaid, and the treating institution.

## VII. RECOMMENDED REGIMENS FOR POST-EXPOSURE PROPHYLAXIS

### RECOMMENDATIONS:

**For children/adolescents 13 years or older, the suggested PEP regimen is zidovudine, lamivudine, and tenofovir. An alternative PEP regimen for these patients is zidovudine, lamivudine, and nelfinavir (see Table 4).**

**For children 13 years or younger, the suggested PEP regimen is zidovudine, lamivudine, and nelfinavir (see Table 4).**

**When the source 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.**

No clinical studies are available to determine the best regimens for prophylaxis. Our recommendations for drug choices and dosages follow current NYSDOH recommendations for occupational and non-occupational PEP and take into account the current ARV therapy recommendations in Chapter 5: *Pediatric Antiretroviral Therapy*. The recommended regimen for children/adolescents 13 years and older provides potent antiviral activity with a low pill burden and minimal side effects; however, tenofovir has not yet been FDA-approved for children under age 18.

A prophylactic medication regimen using a combination of agents should be started promptly. Indirect evidence (as outlined in the background sections) supports the effectiveness of reverse transcriptase inhibitors in reducing the risk of HIV transmission. Although the most extensive data exist for “monotherapy,” most experts would use three-drug combinations. Although combinations including PIs may be more effective, the likelihood of drug toxicity increases when more drugs are used in combination.

Although the NYSDOH generally recommends a three-drug regimen for PEP, the Committee did not reach consensus. Some believed that the issues of toxicity and poorer adherence with a three-drug regimen warranted use of a two-drug regimen in some cases. Others believed that a three-drug regimen was always preferable. More recently available formulations of medications include combination pills and once-daily dosing that are more convenient. These have not been extensively studied in the context of PEP but have been proven effective in the treatment of HIV infection.

**TABLE 4**  
**RECOMMENDED REGIMENS FOR PEDIATRIC POST-EXPOSURE PROPHYLAXIS AND**  
**DOSING AND SIDE EFFECTS OF RECOMMENDED MEDICATIONS\***

<b>Recommended Regimens</b>	
<b>Children &lt;13 y of age</b>	<b>Children/Adolescents ≥13 y of age</b>
<b>Zidovudine + Lamivudine</b> + <b>Nelfinavir</b>	<b>Zidovudine + Lamivudine (may be given as Combivir)</b> + <b>Tenofovir</b>
<b>Zidovudine (Retrovir, ZDV)</b>	<i>Dosage:</i> 180 mg/m <sup>2</sup> /dose bid (maximum dose 300 mg bid) <i>Formulation:</i> 100-, 300-mg caps; 10 mg/mL solution Combivir = ZDV 300 mg + 3TC 150 mg <i>Side Effects:</i> Bone marrow suppression, anemia, neutropenia, thrombocytopenia, nausea, myalgia, headaches, hepatotoxicity
<b>Lamivudine (Epivir, 3TC)</b>	<i>Dosage:</i> 4 mg/kg/dose bid (maximum dose 150 mg bid) <i>Formulation:</i> 150-mg tabs; 10 mg/mL solution Combivir = ZDV 300 mg + 3TC 150 mg <i>Side Effects:</i> Pancreatitis, peripheral neuropathy
<b>Nelfinavir (Viracept)</b>	<i>Dosage:</i> 50-55 mg/kg/dose bid For children Tanner I-III, maximum dose 1250 mg† For children Tanner IV and V, maximum dose 1250 mg <i>Formulation:</i> 250-mg tabs; 50 mg/g scoop powder <i>Side Effects:</i> Diarrhea, nausea, vomiting, headache
<b>Tenofovir‡ (Viread)</b>	<i>Dosage:</i> 1 tablet qd <i>Formulation:</i> 300 mg tabs <i>Side Effects:</i> Renal toxicity, pancreatitis

\* Consult package inserts for full dosing recommendations, drug interactions, and side effects. The predominant adverse effects of 28-day PEP treatment are malaise, nausea and vomiting, and diarrhea; other listed adverse effects are rare. For infants <4 weeks old, consult dosing recommendations in *Management of the Pregnant Woman Including Prevention of Perinatal HIV Transmission*. Available at: [www.hivguidelines.org](http://www.hivguidelines.org)

† The maximum FDA-approved dose is 1250 mg q12h. Because of the increased clearance of nelfinavir in children as compared to adults, some experts will use dosages as high as 2000 mg q12h in children who are Tanner I, II, or III.

‡ Not approved for children under 18.

Reports of nevirapine-induced hepatotoxicity among people receiving PEP have led to the recommendation that nevirapine not be used as a component of the PEP regimen except in rare situations when there are no other options (e.g., the source's resistance profile dictates its use). Females with CD4 counts >250 cells/mm<sup>3</sup> are at considerably higher risk (12-fold) for hepatic events.<sup>33</sup> Although the mechanism by which nevirapine causes more serious effects in some individuals rather than others is unknown, and it is not known whether all the individuals with serious adverse effects took the gradual step-up dosing of nevirapine as recommended, the potential risk of nevirapine as part of a PEP regimen may outweigh its anticipated benefits. When nevirapine is used, it is crucial that the 14-day lead-in period be strictly followed.

Efavirenz should not be used as part of a PEP regimen in women of childbearing age. Clinicians should use extreme caution when considering abacavir because of the danger of a fatal hypersensitivity reaction if stopped and then started again, as could be the case if the patient is exposed more than once or becomes infected and later needs abacavir for treatment.

The recommended medications can be taken at the same time and with food. The ARV regimen should be continued for 28 days. Arrangements should be made to supply the patient with sufficient medications to complete a course of PEP.

In New York State, the Clinical Education Initiative (CEI) centers maintain a 24-hour telephone contact to assist with questions regarding PEP (see Appendix II).

## VIII. FOLLOW-UP MONITORING FOR PATIENTS RECEIVING PEP

### RECOMMENDATIONS:

**Initial follow-up of the exposed child should occur within 2 to 3 days to review medication regimen, assess psychosocial status of child and family, and arrange appropriate referrals (e.g., psychosocial counseling after sexual assault).**

**Clinicians should closely monitor patients receiving PEP to detect ARV-induced toxicities. Arrangements should be made for clinical follow-up at 2 weeks and 4 weeks; CBC and serum liver enzymes should be repeated at 4 weeks (see Table 5).**

**HIV testing should be repeated at 1, 3, and 6 months after exposure.**

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

Post-exposure care involves simultaneous attention to multiple issues: the emotional state of the exposed patient and the patient's family, adherence to the PEP regimen, monitoring for potential adverse effects, and sequential HIV testing to exclude acquisition of infection.

<b>TABLE 5 MONITORING RECOMMENDATIONS AFTER INITIATION OF PEP</b>				
	<b>Clinic Visit*</b>	<b>CBC with Differential</b>	<b>Serum Liver Enzymes</b>	<b>HIV Antibody*</b>
<b>Baseline</b>	X	X	X	X
<b>Week 1</b>	X			
<b>Week 2</b>	X†			
<b>Month 1</b>	X	X	X	X
<b>Month 3</b>	X			X
<b>Month 6</b>	X			X

\* Recommended even if PEP is declined.

† Either clinic visit or phone call.

## IX. PEP FOLLOWING EXPOSURES TO OTHER INFECTIOUS AGENTS

### RECOMMENDATIONS:

**If the exposed child/adolescent is not fully immunized against hepatitis B, the child/adolescent should complete the hepatitis B vaccine series, with the next scheduled vaccine dose being given immediately. If the source is known to be HbsAg(+), the child should receive hepatitis B immune globulin in addition to completing the hepatitis B vaccine series.**

**If the child has been previously vaccinated against hepatitis B, the child's serostatus should be determined. If the child has serologic immunity to hepatitis B, no further action is necessary. If the child does not have serologic immunity but there is documentation of previous vaccination, the clinician should administer a booster vaccine and reevaluate serologic status in 1 month to determine whether full revaccination is necessary.**

**The baseline hepatitis C serologic status of the exposed child should be determined in cases of percutaneous exposure. There are currently no recommendations for prophylaxis for HCV. Repeat testing for hepatitis C serologic status should be performed at 6 months. Repeat testing for hepatitis C serologic status or PCR for HCV may be considered at 2 to 4 weeks after exposure.**

**The tetanus vaccination status of the exposed child should be assessed in cases of percutaneous exposure or bite wound. Tetanus toxoids and tetanus immune globulin should be given if the child's vaccination status is not up-to-date.**

**Bite wounds should be cleansed, and antibiotics should be initiated in cases of severe wounds, deep puncture wounds, and wounds to the face, genitals, or extremities.**

The risk of transmission of HBV from either percutaneous or sexual exposure is significantly greater than the risk of transmission of HIV. The risk of transmission following percutaneous exposures to healthcare workers has been reported to be from 6% to 30% depending on the presence of the hepatitis e antigen. The risk of transmission from a discarded needle may lessen according to how much time has elapsed since the needle was discarded, although HBV is more resistant to environmental conditions than HIV. In addition, most children have been fully immunized against hepatitis B as infants and are not at risk for acquisition of the infection. Determination of the child's antibody status (HBsAb) or verification of the vaccination history should be performed.

The transmission of HCV is less likely than the transmission of HBV and is very unlikely in the setting of a sexual exposure or bite wound. Prophylaxis has not been demonstrated to be effective in preventing the transmission of hepatitis C. Some data from adult studies show that early treatment of hepatitis C may be beneficial.

## **X. PREVENTING EXPOSURES**

### **RECOMMENDATIONS:**

**Children should be instructed in school and at home about potentially risky exposures and how to avoid them.**

**The clinician should discuss reduction of potentially risky behaviors with all children in a manner that is appropriate to their age and developmental stage as a routine component of pediatric care.**

Children should be cautioned about the potential dangers of touching another person's blood, of body piercing and tattooing, and about the more common routes of transmission, such as sexual exposure and intravenous drug use. Children should be taught about inappropriate sexual exposure and encouraged to report such exposures to a trustworthy adult. Coaches and children engaging in sports should be aware of protective measures for all players, including the use of mouth guards. Gloves and first aid equipment should be available at all sports activities as well as in classrooms and at other school and social activities.

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## **APPENDIX A**

### **SEXUAL ASSAULT FORENSIC EXAMINER (SAFE)\* PROGRAM**

The Sexual Assault Forensic Examiner (SAFE) program is a collaborative effort in which rape crisis advocates, specially trained health care providers, law enforcement, campus public safety, the district attorney, and other service providers work together to meet the needs of the sexual assault survivor.

\*Other acronyms used to describe these programs are SAE (Sexual Assault Examiner), SANE (Sexual Assault Nurse Examiner) or SART (Sexual Assault Response Team).

The general objectives for Sexual Assault Forensic Examiner programs are:

1. To provide the survivor of sexual assault with victim-centered, sensitive care which includes a comprehensive assessment and evaluation.
2. To ensure quality evidence collection by a specially trained healthcare practitioner.
3. To provide expert testimony when needed if the survivor reports the crime.

To become a Sexual Assault Forensic Examiner, licensed healthcare professionals receive training in:

1. Comprehensive history taking and evaluation
2. Cultural competency
3. Injury detection and documentation
4. Emergency contraception
5. Management of potential exposure to sexually transmitted diseases
6. Post-exposure management for HIV and hepatitis B and C
7. Use of special equipment (colposcope, anoscope, forensic photography, etc.)
8. Evidence collection and chain of custody
9. Community resources
10. Courtroom testifying

To find out about Sexual Assault Forensic Examiner programs in your area, contact your local rape crisis or crime victim services program.

For more information about Sexual Assault Forensic Examiner programs in New York State or any sexual assault issues, contact:

New York State Coalition Against Sexual Assault  
63 Colvin Avenue  
Albany, NY 12206  
518-482-4222 phone  
518-482-4248 fax  
[www.nyscasa.org](http://www.nyscasa.org)

## **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

**RENSSELAER 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

**STEBEN 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