HIV NPEP *Plan of Action*

for Victims of Sexual Assault in Kentucky

prepared by:
Kentucky Council on Domestic Violence and Sexual Assault
Sexual Assault Response Team Advisory Committee

in consultation with:
Kentucky AIDS Education Training Center

Offering Non-occupational Post-Exposure Prophylaxis (NPEP)
Recommendations for Health Care Providers

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The Sexual Assault Response Team Advisory Committee

The Sexual Assault Response Team Advisory Committee operates pursuant to KRS 403.707 with membership representing the following:

Kentucky State Police, *Co-Chair*
Kentucky Association of Sexual Assault Programs, *Co-Chair*
Kentucky Board of Nursing
Kentucky Nurses Association
Kentucky Hospital Association
Kentucky State Police Forensic Laboratories
CHFS, Family Violence Prevention Branch
Office of Victims Advocacy, Office of the Attorney General
Sexual Assault Nurse Examiner, Physician, Prosecuting Attorney, and SART Team Member

NPEP Subcommittee of the SART Advisory Committee

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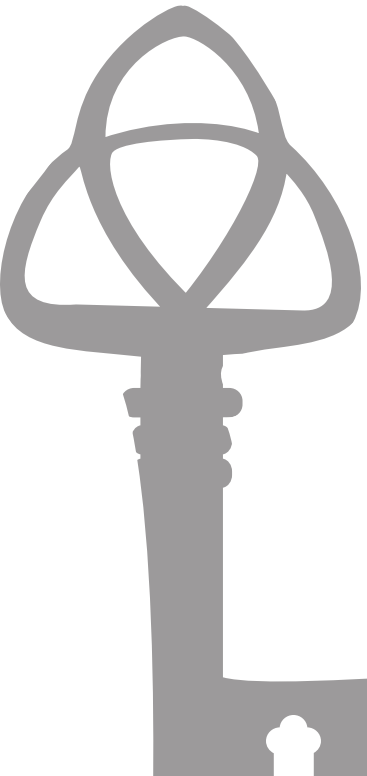

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Crime Victims Compensation Board

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INTRODUCTION.

Contracting Human Immunodeficiency Virus (HIV) as a result of sexual violence is an overwhelming fear for many victims. This document presents a plan of action to enable healthcare providers to address this fear. Post exposure prophylaxis for non-occupational exposures (NPEP) involves the provision of antiretroviral medications to prevent HIV transmission. The risk of HIV transmission with some non-occupational exposures may be similar or of higher risk than with occupational exposures.

Though the risk of HIV infection is not new, statewide efforts to address HIV non-occupational post exposure prophylaxis (NPEP) for victims of sexual assault are relatively young. These efforts have emerged in the wake of two critical policy developments: 1) the U.S. Department of Health and Human Services guidelines have been updated to endorse universal provision of NPEP for those patients with reported sexual assault, and 2) Kentucky's Office of the Attorney General (OAG) subsequently issued an Opinion stating that HIV NPEP is a part of basic treatment for sexual assault victims, and as such, must be paid for by state funds administered by the Crime Victims Compensation Board.

In response to those updates, the Sexual Assault Response Team Advisory Committee, in conjunction with the Kentucky AIDS Education Training Center, and other professionals across the Commonwealth, produced this Plan of Action for the provision of NPEP in regard to those individuals seeking care after sexual assault.

These recommendations are designed to provide guidance to health care providers who are managing potential non-occupational HIV exposures that occur as a result of sexual assault. The focus is on the following areas:

- Deciding who should be offered NPEP based upon the details of the exposure;
- Deciding what medications and services to provide; and
- Determining how to provide these medications and services.

Organization and Use of this Document.

The document contains the key elements regarding non-occupational post exposure prophylaxis (NPEP) use and should be used as a quick reference only. Frequent changes in standards of HIV care require that the treatment guidelines be carefully reviewed by the medical team in your facility to assure that they conform to acceptable local and current approaches. Medical treatment updates are posted frequently to several websites, including the http://www.aidsinfo.nih.gov and www.cdc.gov site. It is recommended that every provider be familiar with all relevant guidelines.

The documents and forms contained in this document may be reproduced for use. Please note that these treatment recommendations are not intended to replace clinical research literature or current United States Public Health Service (USPHS) guidelines, and may not include the full range of treatment options for all patients.

It is recommended that a provider contact the Kentucky AIDS Education and Training Center (KY AETC) warmline or UKMD line and ask for the infectious disease (ID) physician on call, if there are questions regarding the provision of NPEP.

Copies of this Document.

Copies of this document may be obtained from the Kentucky Association of Sexual Assault Programs' website: www.kasap.org or by calling 502-226-2704.

If you encounter a newly diagnosed HIV patient (through sexual assault or otherwise) make appropriate regional referral.

HIV Shortcut Card

SUPPORT • EDUCATE • MOTIVATE
KY AETC
Kentucky AIDS Education Training Center

1. To Consult on HIV care with an ID specialist or pharmacist
   Call KY AETC Warm Line: 866.777.9969
   Call UK MD (24/7): 866.257.6845
2. To refer a new HIV patient to care:
   Lexington Area: 859.323.1688
   Louisville Area: 502.561.8844
   Paducah Area: 270.444.8183
   Henderson Area: 270.826.0200
3. To discuss Clinical Trials available for HIV:
   Call: 859.323.6327

Kentucky AIDS Education Training Center
Chandler Medical Center, MN672
Lexington, Kentucky 40536
(P) 859.323.9969 (F) 859.323.8826
Online: www.mc.uky.edu/kyaetc

Definitions.

Non-occupational exposure is any direct mucosal, percutaneous or intravenous contact with potentially infectious body fluids that occurs outside perinatal or occupational situations.

Post-exposure Prophylaxis (PEP) is the provision of medications or treatment to prevent transmission of a disease or illness following an occupational or perinatal exposure.

Non-occupational Post-exposure Prophylaxis (NPEP) is the provision of medications or treatment to prevent the transmission of a disease or illness following any direct mucosal, percutaneous or intravenous contact with potentially infectious body fluids that occurs outside perinatal or occupational situations.

WHO SHOULD BE OFFERED NPEP?

NPEP should be offered to HIV uninfected or unknown status individuals presenting within 72 hours of a potential exposure to HIV. It is the responsibility of the health care provider to help the patient who is seeking NPEP to realistically assess his/her risk of acquiring HIV infection, to manage their emotional reactions, and to make an informed decision about taking NPEP.

Assessing the likelihood of HIV infection & HIV status following exposure includes two factors:

1. Did a potentially infectious body fluid from the exposure source come into contact with the exposed individual's mucous membrane or non-intact skin?

   -**AND**-

2. Is the exposure source known to be HIV infected or at risk of having HIV infection?

Individuals at highest risk of acquiring HIV infection from their specific exposure are expected to benefit most from NPEP. Potentially exposed individuals should be assisted in evaluating their risk based upon the type of sexual contact or other exposure, and the likelihood that the exposure source is HIV infected.

Assessing the Risk of the Exposure.

If a potentially infectious body fluid (e.g., blood or blood products, genital secretions, peritoneal, pleural or cerebrospinal fluids but NOT saliva, tears, or sweat) was in contact with a mucous membrane (e.g., eye, oral, nasal, or genital mucosa) or non-intact skin (punctures, cut, or substantially abraded), infection is possible and consideration of NPEP is warranted.

The following activities are associated with HIV transmission risk. Note that additional factors that might enhance sexual transmission, such as trauma, genital ulcer disease, or cervical ectopy, should also be considered:

- Receptive anal intercourse (1-3% per- contact transmission risk)
- Shared injection drug use equipment (0.67% per-contact transmission risk)
- Insertive anal intercourse (0.1 – 1% per-contact transmission risk).
- Receptive vaginal intercourse (0.1 - 1% per-contact transmission risk).
- Insertive vaginal intercourse (less than 0.1 % per-contact transmission risk).
- Other potentially infectious body fluid on a mucous membrane or non-intact skin.
- Receptive oral intercourse with ejaculation (case reports only: consider NPEP).

Assessing the Likelihood that the Source of Exposure is HIV-Infected.

In all cases of sexual assault, NPEP should be considered. It is reasonable to offer NPEP to individuals following sexual assault by unknown assailant. It is also reasonable to offer NPEP for women who have been sexually assaulted by men who are known to them, but whose sexual and injection drug use history is not known with confidence. Multiple other factors can be considered to determine the likelihood that the source of exposure is HIV-infected.

Individuals at highest risk of acquiring HIV infection from their specific exposure are expected to benefit most from NPEP

There is a growing incidence of HIV infection among the female sex partners of intravenous drug users (IDUs) or men who deny having sex with men, particularly in some African American and Latino communities. Local demographics may also be taken into consideration. Determining the level of confidence regarding the source's description of HIV status is a shared task of the patient and health care provider.

Source Plasma Viral Load

An undetected or low plasma HIV RNA level or plasma viral load does not ensure that genital secretions are not infectious, due to viral compartmentalization.

Source HIV Testing

If an exposure source of unknown HIV status is available and consents, then HIV testing of the source should be encouraged, using a rapid or standard HIV antibody test. If a rapid test is negative or nonreactive, NPEP should be deferred unless there is a high index of suspicion that the source may be in the seronegative window period of infection. The seronegative window is on average from 3 to 6 months following time of exposure. If using a confirmatory test, NPEP can be discontinued when the results come back with the same caveat.

Multiple Exposures

Some individuals will present for NPEP following a series of exposures, some of which are within, and others outside, the 72 hours cut-off. It will be up to the judgment of the individual health care provider to determine when NPEP should be offered and when it should not be offered in such circumstances. It is not unreasonable to offer NPEP, however, the reduced likelihood of being able to prevent HIV infection because of the earlier exposures should be explained to the patient.

Assessing HIV Status

All individuals presenting for NPEP should be evaluated for the likelihood of pre-existing HIV infection. The following information should be obtained: 1) if patient has ever been tested, if so, date of last HIV test, and 2) the number and type of unprotected exposures since the last test. The likelihood of pre-existing HIV infection should be reviewed with the patient prior to NPEP prescription. If pre-existing HIV infection is likely, this information should be integrated into the risk-benefit assessment when the patient is deciding about using NPEP. In addition, if the likelihood of pre-existing HIV infection is high, a three-drug regimen should be considered.

WHO SHOULD NOT BE OFFERED NPEP?

NPEP is not indicated for perceived exposures of negligible or no conceivable risk (e.g., kissing, oral-anal contact, mutual masturbation without skin breakdown, bites not involving blood, cunnilingus not involving blood exposure, unprotected receptive oral intercourse without ejaculation {although pre-ejaculate in the presence of oral pathology may carry some risk}, unprotected insertive oral sex, etc.). Clinicians should be willing to decline requests for NPEP and provide supportive counseling and referrals in these situations. In some situations (e.g., a needle stick from a discarded syringe) the risk is simply not known, and individual judgment must be used.

Children and Adolescents

These guidelines do not specifically address the special needs of children and adolescents.
Refer to local policy of Children's Hospital or contact your local Children's Advocacy Center.

Pregnancy

Pregnant women can receive NPEP, but should not be given Efavirenz or didanosine. Also, do not combine didanosine and stavudine.

For more information about antiretroviral use in pregnancy, refer to the Public Health Service Task Force Recommendations for the Use of Antiretroviral Drugs in Pregnant Women Infected with HIV-1 for Maternal Health and for Reducing Peri-natal HIV-1 Transmission in the United States at:
http://www.aidsinfo.nih.gov/guidelines/

Other Community Exposure

This document is solely for the setting of sexual assault. For other community exposures, refer to the current CDC NPEP guidelines. www.cdc.gov

Timing of NPEP Initiation.

Initiate NPEP as early as possible after the exposure. According to animal models of the natural history of HIV acquisition following exposure and of NPEP interventions, NPEP will be more effective the sooner it is started. After initial evaluation the patient may be given a 7-day starter pack.

Evidence suggests a 72-hour time limit for the initiation of NPEP. Risks of providing NPEP after the 72-hour limit of likely effectiveness include: 1) the development of drug resistance if a regimen is used and it is not fully suppressive; 2) the risk of further development of resistance if resistant virus was transmitted; and 3) the emotional difficulty patients may have discontinuing medication once it has been started if they do become HIV infected.

There is no human evidence that suggest that NPEP alters the natural history of breakthrough infections.

Exposure Characteristics and Indications for NPEP

TABLE 1

Exposure Characteristic	Offer NPEP:
1. Timing	As soon as possible, and no later than 72 hours following exposure. - AND IF -
2. Exposure type	• Receptive anal intercourse; or • Insertive anal intercourse; or • Receptive vaginal intercourse; or • Insertive vaginal intercourse; or • Other potentially infectious body fluid contact on a mucous membrane or non-intact skin; or • Receptive oral intercourse with ejaculation (consider due to lower risk; if oral pathology, risk is higher); or • Shared injection drug use equipment - AND IF -
3. Exposure source if known *HIV testing should be a routine part of medical care for all individuals aged 13-64, no matter the risk factors identified. For those individuals determined to have risk factors, repeat HIV testing should be conducted annually. [CDC Guidelines. 2006.]*	• Known HIV-infected; or • Men who have sex with men (MSM) of unknown HIV status; or • Injection drug user (IDU) or unknown HIV status; or • Anonymous (consider); or • Known but with unknown HIV status and risk factor history (consider)

NPEP Interventions	
TABLE 2	
Component	Recommended
Medications	• Medication regimen › Preferred regimen consists of two nucleoside analogues zidovudine and lamivudine (coformulated as Combivir) plus a boosted protease inhibitor lopinavir and ritonavir (coformulated as Kaletra). If the exposure source's medication history is accessible, obtain expert antiretroviral resistance consultation immediately. If local consultation is unavailable, call the National HIV Telephone Consultation Service at (800) 933.3413. The hours are: 6 a.m. – 5 p.m., Pacific Standard Time (PST), Monday – Friday. Note that this service is available for health care providers only. Consider academic hospital infectious disease consultation after hours.
Duration of therapy	• 28 Days
Testing and interventions	• Initial exam (day 1 of treatment): CBC, CMP, HIV, Hepatitis B testing, provision of 7 day starter pack and 28 days of anti-nausea medication • Follow up (prior to day 8): Office visit, Western Blot HIV test, provision of HIV medication for days 8-14. • Follow up (prior to day 14): Office visit, CBC, CMP, and pregnancy test, and provision of final 14 days of HIV medication. • Follow up (at or around day 28): Office visit, final CBC and CMP.
Follow-up HIV counseling and testing	• Baseline • Six weeks • Three months • Six months
Patient Education and Referrals	• Medication adherence counseling • Risk-reduction counseling • Referrals for substance use and mental health treatment as appropriate

In all cases of sexual assault,
NPEP should be considered.

NPEP Action 1: EVALUATION

Evaluation for the exposed patient should be treated with the highest level of confidentiality. HIV reporting should take place as required by state laws.

Circumstances of the exposure and NPEP management should be recorded in the medical record. Details should include:

- Date and time of exposure (is it within 72-hours?)
- Details of the incident-where and how exposure occurred, exposure sites on body
- Details of the exposure: type and amount of fluid or material, severity of exposure
- Details about exposure source, if available:
  - HIV, Hepatitis B and Hepatitis C status
  - If the source is HIV-infected, determine the stage of disease, HIV viral load, current and previous antiretroviral therapy and antiretroviral resistance information
- Details about the exposed patient:
  - Hepatitis A and Hepatitis B vaccination and vaccine-response status
  - Other medical conditions, drug allergies, and medications
  - Pregnancy and breast-feeding status

Management of potential exposures requires a baseline evaluation. The following baseline tests are recommended:

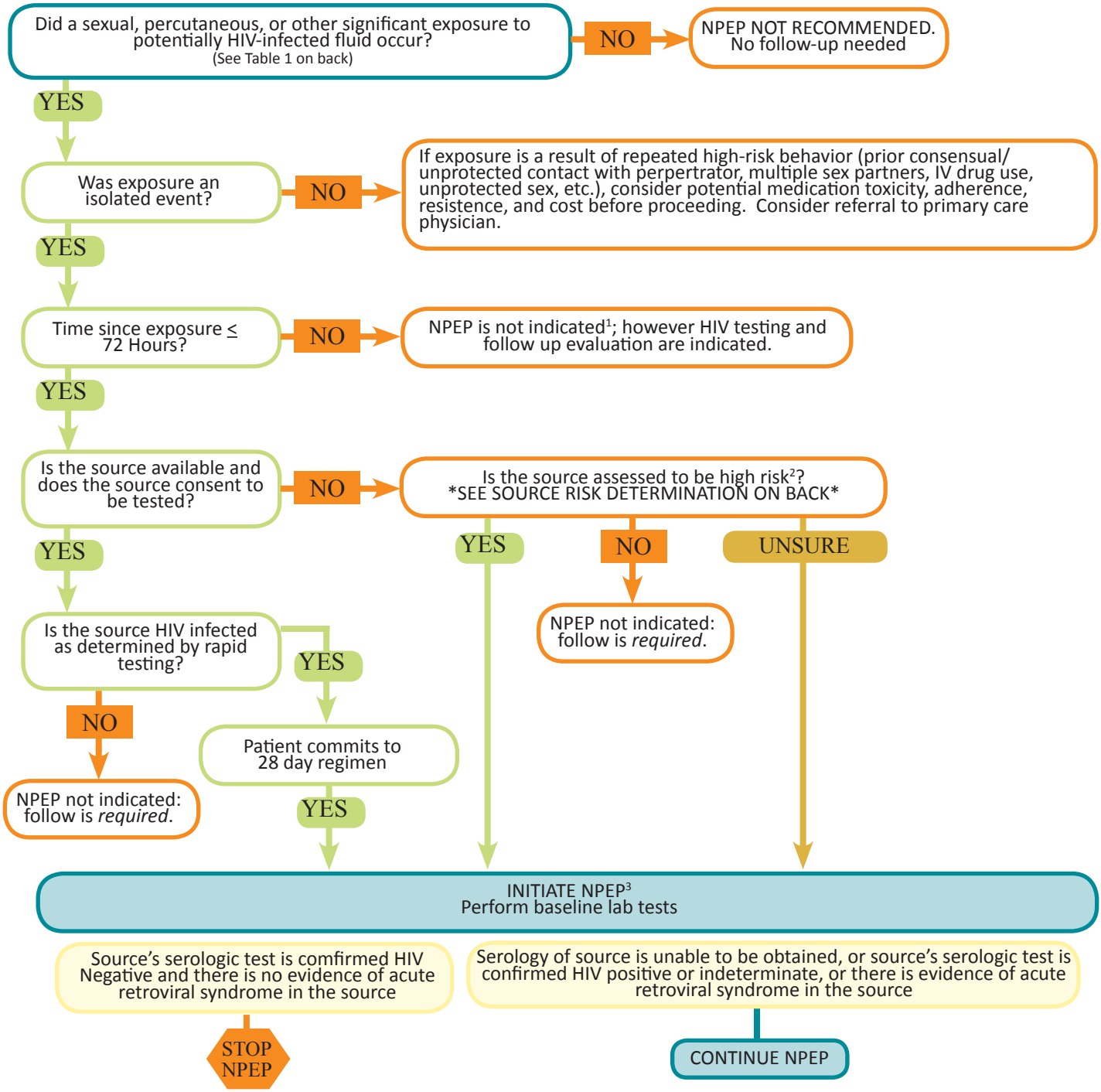
- Screening and prophylaxis for other STIs
- Consider serological testing for Hepatitis B and Hepatitis C and Hepatitis B vaccination
- Pregnancy testing, as appropriate
- Assess need for emergency hormonal contraception

NPEP Action 2: RISK ASSESSMENT

The exposure should be evaluated for potential to transmit HIV based on (1) the type of body substance involved, (2) the route, and (3) HIV status of the source patient.

- Refer to following algorithm for risk assessment.

GUIDELINES FOR OFFERING HIV NPEP TO PATIENTS OF SEXUAL ASSAULT



1. Decisions should be individualized, weighing the likelihood of transmission against the potential benefits and risks of treatment.
2. In sexual assault the decision to initiate NPEP is based on whether a significant exposure has occurred rather than on the risk behavior of the alleged assailant.
3. If the patient is too distraught to engage in a discussion about and/or commitment to the drug regimen at the initial assessment, the clinician should offer a first dose of the medication and make arrangements for a follow-up within 24 hours to further discuss the indications for NPEP.

Modified from New York State Department of Health AIDS Institute | www.hivguidelines.org

Guidelines for Offering HIV Post Exposure Prophylaxis (PEP) to patients of Sexual Assault

TABLE 1	
Types of Exposure That Do Not Warrant NPEP	Types of Exposure That Should Prompt Consideration of NPEP
• Kissing • Oral-to-Oral contact without mucosal damage • 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	• 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 needle sticks, human bites, accidents)

SOURCE THAT MAY HAVE INCREASED RISK FOR HIV INFECTION

Sources with a history of multiple sex 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 and/or drugs

Patient Name:

Account Number:

Date:

☐ Pt. commits to 28 day treatment
☐ Starter pack given
☐ Patient declined
☐ Treatment education given
☐ Pt. verbalizes understanding

Patient referred to:

RN or MD signature

Modified from New York State Department of Health AIDS Institute
www.hivguidelines.org

NPEP Action 3: SOURCE ASSESSMENT

Evaluate the exposure source only if known/available

Known HIV infection	Unknown HIV infection
• Obtain history of antiretroviral medication, recent viral load, CD4 cell count, and date of results • Consider evaluation and testing for other sexually transmitted infections, including Hepatitis B and Hepatitis C	• Obtain risk history and rapid HIV test • Consider evaluation and testing for other sexually transmitted infections, including Hepatitis B and Hepatitis C

Regardless of HIV status, assess and assist with access to medical care, social support services, and risk reduction counseling.

Treatment of the patient is prioritized. Treatment should not be delayed while waiting for lab results. All exposures sustained during sexual assault should be considered a risk for HIV transmission.

NPEP Action 4: TREATMENT

If (1) the exposure is within 72-hour, (2) the exposure is assessed as a risk by the health care provider, and (3) the patient consents to 28 days of NPEP treatment the following is needed:

- Consent for HIV testing and NPEP treatment
- Documentation of patient education regarding testing and treatment course of action
- Complete blood count with differential
- Serum liver enzymes
- Blood urea nitrogen/creatinine
- Urinalysis

A 7 day starter pack with the preferred regimen will be provided at time of initial evaluation. Medications can then be changed at follow up if appropriate based on source patient resistance (if available), efficacy data, toxicity, pill burden/ease of dosing, potential drug interactions, cost, and pregnancy risk. Prophylactic antiemetic and antidiarrhea agents can be used if necessary.

Practitioner consultation with a specialist is recommended.

- **UK MD (24/7): 859.257.6845**
- **Centers for Disease Control (CDC) HOTLINE: 1.800.232.4636**
- **NPEP HOTLINE 1.888.448.4911**

NOTE:
If consultation is not immediately available, **NPEP should not be delayed**; changes can be made as needed after NPEP has been initiated. If source is found to be HIV negative or nonreactive, NPEP should be discontinued. Delaying NPEP therapy in order to obtain resistance test results (genotyping or phenotyping) for the purposes of selecting more specific therapy is not advised.
Exposed persons are frequently unable to complete NPEP regimens due to side effects. Providing prophylactic symptom management can improve adherence.

SPECIFIC TREATMENT RECOMMENDATION: 7-DAY STARTER PACK

Preferred Regimen	A protease inhibitor based regimen with two nucleoside analogues: Lopinavir / ritonavir (coformulated as Kaletra) plus Lamivudine and zidovudine (coformulated as Combivir)

- Alternative regimens may be used if indicated by reaction or other medical indicator. See CDC recommendations for alternative treatment and obtain expert consulation.
- **NOTE:** Efavirenz (EFV) should be avoided in pregnant women and women of child bearing potential. Pregnant women should not be given didanosine. Do not combine didanosine and stavudine.

HIV NPEP Medication Factsheet

Length of Therapy and Amount Dispensed

- The total NPEP treatment is 28 days
- NPEP should not be administered for less than 28 days unless:
  - › The source is determined to be uninfected via Western Blot
  - › The exposed individual is determined to be HIV infected per Western Blot
  - › There are intolerable side effects and no alternatives are available
  - › The exposed individual changes his or her mind about NPEP after re-examining the risks and benefits
- Individual health care providers should determine a schedule for dispensing NPEP
- Dispensing an initial week of medication allows staff to assess symptoms, provide counseling, and receive initial HIV test results before dispensing additional NPEP
- Dispensing the entire 28-day course could result in wasted medications if side effects warrant changes in medication or the patient decides not to continue NPEP

Initial Medication Choices and When to Consult an Expert

- In the absence of information about the exposure source's antiretroviral history, or if source is naïve to the medication, the preferred two-drug regimen is Combvir (ZDV + lamivudine)- one pill twice a day plus Kaletra (250/50) 2 pills twice a day. This is the medication in the 7 day starter pack.
- If the exposure source's medication and/or drug resistance history is accessible through health care providers without expertise in retroviral resistance, should consult an expert immediately
- If alternate drugs are required, refer to CDC guidelines (www.cdc.gov) in combination with expert consultation.
- If local consultation is not available call the National HIV Telephone Consultation Service at 800-933-3413 (6 am to 5 pm PST, Monday through Friday- for healthcare providers only)
- Consider academic hospital infectious disease consultation after hours
- NPEP medication should not be delayed more than 2 to 4 hours while accessing consultation
  - › The starter pack should be initiated if there is a delay.
  - › The medication regimen can be changed once this information is available
- If one of these drugs is prescribed by a health care professional without expertise, an expert should be consulted regarding side effects
- Drug interactions are also important with these drugs and a full review of all medication is important

Managing Side Effects, Including Medication Changes

- Patients should be given information regarding getting medical assistance in the case of side effects
- Common side effects seen with Combivir include nausea, fatigue, and headaches
- Common side effects seen with Kaletra are diarrhea, fatigue, headache, and nausea.
- It is not clear how much of these symptoms are from the medication or from the emotional impact of the situation
- Taking the pills with food reduces nausea.
- Anti-emetics and analgesics can be prescribed as indicated.
- In some cases NPEP regimen may be modified due to adverse effects in reference with current guidelines and expert consultation.

Adherence to Medication

- Adherence to medication counseling should be strongly encouraged to all patients
- Patients should take a missed dose if it is recognized within approximately six hours of when the dose was scheduled for a BID medication, or 12 hours for a once a day medication
- If three or more days are missed consecutively, the patient should be advised to discontinue NPEP medication course

Post-Coital Contraception

- Post-coital contraception should be offered when indicated
- In order to reduce the cumulative nausea effect of these medications, it is suggested that the contraceptive be delayed at least one hour after the initial dose of Combivir
- Pre-medicating with an anti-emetic is an option

HIV TESTING

Rapid ELISA Testing

- HIV testing should be routine, using either rapid or confirmatory testing
- Patients seeking NPEP may fall into a high-risk category for previous HIV infection
  › In this setting, the positive rapid HIV test has a very high positive predictive value and thus deferring NPEP in individuals with a positive or reactive test is reasonable
- Individuals testing positive or reactive on a rapid test should be given the option of initial NPEP pending the results of the confirmatory test
- In this case, a three drug regimen should be used

HIV Testing for the Exposure Source

- HIV testing for the source of exposure should be encouraged
- If an exposure source tests HIV-negative or nonreactive, NPEP should be deferred or discontinued unless there is a very high likelihood for pre-seroconversion acute HIV infection

Timing of Initial and Follow-Up Testing

- An HIV test should be obtained upon presentation for NPEP
- If NPEP medications are provided by telephone prior to in-person appointments, no more than three to four days of medication should be provided prior to HIV antibody testing
- Repeat testing should be encouraged at two, three, and six months following the exposure

Referrals

- Mental health and substance abuse problems may contribute significantly to the risk of subsequent exposures
- NPEP should be provided together with services that address ongoing needs of patients regarding HIV risk behaviors
- Health care providers should be aware of local resources for mental health care and substance abuse treatment
  › Rape Crisis Center services to mitigate sexual assault trauma (1-800-656-HOPE)
  › HIV Hotline for patients needing HIV specific support (1-800-CDC-INFO)
- Primary care referrals should also be available when indicated

Patients who are victims of sexual violence should be encouraged to seek mental health support. This is especially true for victims who must also consider potential exposure to HIV. Regional rape crisis centers provide victim advocacy 24/7 and can link patients to mental health services. See rape crisis center map and contact information in appendix.

BILLING

The patient ***shall not*** be billed for NPEP treatment by either the pharmacy or the medical provider.

Per CVCB protocol, the initial medical service provider shall provide the patient with a signed CVCB voucher to advise pharmacies and follow up health care providers that the prescription and related medical services qualify for CVCB payment. (initial and follow up tests including HIV, CBC, CMP, Hep B, and pregnancy; 28 days of HIV medication; 28 days of anti-nausea medication; and, 3 office visits for follow up) The Crime Victims Compensation Board (CVCB) will provide payment to medical service providers and pharmacies who submit documentation according to CVCB guidelines. Service providers may access the payment request form and further information at: www.cvcb.ky.gov.

NOTE: Payment for the Sexual Assault Forensic-Medical (SAFE Exam or rape kit exam) shall be completed separately per previously established guidelines.

Other Laboratory Testing

Routine Testing for Toxicity

- Routine baseline and follow-up laboratory studies to assess for toxicity are not indicated unless there is a specific clinical concern based upon medical history and/or signs or symptoms

HIV RNA Testing

- HIV RNA testing should not be used to diagnose HIV infection in the absence of signs or symptoms suggestive of HIV seroconversion

Evaluation of Acute or Primary Infection

- Patients with signs or symptoms concerning acute HIV infection should be referred for expert assessment when NPEP is provided outside such an expert clinical context
- Given the nonspecific nature of the signs and symptoms of acute HIV infection, the threshold for referral should be low
- Signs and symptoms can include: low- or high-grade fever, pharyngitis, oral candidiasis, oral or genital ulcers, lymphadenopathy, a macular rash above the groin, diarrhea, abdominal pain, myalgias, arthralgias, headache, stiff neck, or photophobia starting more than three days after a potential exposure to HIV
- Note that many of these signs and symptoms are nonspecific
- Laboratory findings often seen in acute HIV infection include lymphocytopenia, mild-to-moderate thrombocytopenia, and mild transaminitis

STI and Hepatitis Treatment and Vaccination

Based upon the 2010 CDC Treatment Guidelines, assessment for STIs may be deferred per the option of the treatment provider and the victim/survivor. Many specialists recommend preventative therapy at initial examination because follow-up of survivors can be difficult.

The following prophylactic regimen is suggested as preventative therapy:

- Post-exposure hepatitis B vaccination, without HBIG, should adequately protect against HBV infection. Hepatitis B vaccination should be administered to sexual assault victims at the time of the initial examination if they have not been previously vaccinated. Follow-up doses of vaccine should be administered 1-2 and 4-6 months after the first dose.
- An empiric antimicrobial regimen for Chlamydia, gonorrhea, trichomonas, and BV.
- EC should be offered if the post assault could result in pregnancy in the survivor.

Recommended Regimens:

- **Ceftriaxone** (250 mg IM in a single dose), **AND**
- **Metronidazole** (2g orally in a single dose), **AND**
- **Azithromycin** (1g orally in a single dose), OR **Doxycycline** (100mg orally 2x a day for 7 days)

Pregnancy Testing

- All women of child bearing potential should be tested for pregnancy
- If the presenting exposure is vaginal they should return for repeat testing if their menstrual cycle is delayed
- Pregnant women can receive NPEP but should not be given Efavirenz or didasnosine plus stavudine
- For more information about antiretroviral use in pregnancy, refer to the Public Health Service Task Force Recommendations for the Use of Antiretroviral Drugs in Pregnant Women Infected with HIV-1 for Maternal Health and for Reducing Perinatal HIV-1 Transmission in the US at: http://www.cdc.gov or www.aidsinfo.nih.gov/guidelines

NPEP Action 5: FOLLOW-UP/REFERRAL

How to make a referral for NPEP follow-up:

Option (1): Each facility or sexual assault examination provider should elicit a relationship with a qualified medical provider who is knowledgeable about HIV treatment and NPEP; who has the ability to receive patients within 3-5 days of the initial exam and referral. The referral facility should be aware of the billing procedures and have the capacity for diagnostic laboratory testing.

Option (2): The initial facility healthcare provider/physician may have the patient return to their facility for follow up treatment if no other option is available.

Option (3): If there is not an established relationship and/or no physician available then sexual assault victims who have been assessed by a physician and have met the criteria for NPEP can be referred to:

a) Another primary care provider; or
b) A local/regional infectious disease physician

THE INITIAL EXAMINING PHYSICIAN SHOULD PROVIDE AN INITIAL NPEP PACK AND REFER FOR FOLLOW-UP, REGARDLESS OF WHETHER OR NOT THE PATIENT COMPLETES A SEXUAL ASSAULT EVIDENCE COLLECTION KIT.

Summary Overview for Other Service Providers

PHARMACY CONSIDERATIONS

Pharmacists will play a role in the dispensing of NPEP regimens as well as in providing counseling regarding proper medication taking behavior and expected adverse effects.

Pharmacists serve as a medication information resource to patients on NPEP throughout the 28 day course of therapy

Pharmacists with specific questions regarding NPEP therapy can contact the NPEP hotline or access specific pharmacy and medical information by contacting the Kentucky AIDS Education Training Center (KYAETC) hotline [866-323-9969 (weekdays 7:30-4:00 PM EDT) & 859-257-6845 (24/7, ask for the ID Physician on call]. KYAETC can provide access to medical and pharmacy personal that specialize in HIV care.

Pharmacists should provide all NPEP patients with extensive counseling regarding common and uncommon medication side effects. Additionally, patients should be counseled with regards to the importance of completing an entire 28 day course of therapy without missed doses. Additionally, pharmacists should be prepared to counsel patients regarding safer sex practices until such time that STI testing is negative. This may include information regarding the use of various barrier techniques such as latex or polyurethane condoms.

All NPEP medications should be taken when available concurrently. No medications should be dispensed as part of an NPEP regimen if all medications are not available at the same time.

Certain antiretroviral medications may interact with other prescription medications either rendering the NPEP medications ineffective or potentially interacting in a fashion that increases drug toxicity. When NPEP is prescribed to a patient receiving other prescription and non-prescription medications a complete drug profile review should take place to assess for any drug-drug interactions. Information regarding drug-drug interactions between

antiretrovirals and other medications are available at the CDC NPEP site. Additional information may be provided by contacting the KYAETC hotline [866-323-9969 (weekdays 7:30-4:00 PM EDT) & 859-257-6845 (24/7, ask for the ID Physician on call]

Pharmacists without immediate access to any medications prescribed as part of an NPEP regimen should be prepared to refer patients to another provider who can dispense these medications in a timely fashion. Pharmacists should be cognizant of the time sensitive therapeutic nature of NPEP regimens and should make every effort to prioritize the dispensing of NPEP regimens. This may especially be an issue in rural areas of the Commonwealth where general dispensing of antiretroviral medications may be less common.

In order to ensure more timely access of NPEP medications to patients other providers should be aware that the use of "phone-in" oral prescriptions may result in faster dispensing and avoid situations where drug access might be limited.

Billing: Due to the time sensitive and emergent therapeutic nature of the NPEP regimens … dispensing of these drugs should not be delayed due to billing issues. Coverage for NPEP is provided by the Crime Victims Compensation Board as outlined in SF-E: BILLING INFORMATION in the back of this document.

RAPE CRISIS CENTER ADVOCATE CONSIDERATIONS

Rape Crisis Center (RCC) Advocates are tasked with providing support and information to victims. Although medical personnel will provide information for clients regarding treatment and testing, it is important for advocates to have some understanding of the protocol to best advocate for the client.

For the Rape Crisis Center:

Advanced Preparation:
Every program should do some preliminary work in and with their community prior to needing to respond to a client who may receive NPEP. Program staff should work with Pharmacies, Doctors, and ER staff.

In Working with the Pharmacy:

- Determine which local pharmacies have the medications in-stock or can order them quickly.
- Develop a relationship with these pharmacies. Talk with them about the treatment, the need for response to clients who are victims of sexual violence, and the billing process.
  - › Take sample forms to the pharmacist so that they will recognize the documents and respond appropriately when a client comes for NPEP medication.
  - › Provide the pharmacist with contact information for the Crime Victims Compensation Board (www.cvcb.ky.gov , 1-800-469-2120) and for your office.
  - › Provide pharmacist with CDC contact information – website: www.cdc.gov, 1-800-CDC-INFO.

In Working with the Doctor:

- Determine if there is a local infectious disease or other MD in your area who will
  - › Accept referrals and
  - › Accept CVCB billing
- Develop a relationship with this office
  - › Follow up with the billing service/staff to insure understanding of the process
  - › Provide examples of the forms and information re: billing CVCB
  - › Provide contact information for the CVCB and your office
  - › Provide contact information for the Ky. AIDS Education Center Warmline: 1-866-777-9969
  - › Provide contact information for the National HIV Telephone Consultation Service at (800) 933-3413 with hours of 6a.m. to 5 p.m. PST Monday – Friday. http://www.ucsf.edu/hivcntr/Warmline/index.html (this service is available for health care providers only).

In Working with the Emergency Room Staff:

- Meet with the ER Nurse Manager or other management in the ER to review and discuss this protocol.
- Build a relationship with ER Nurse Manager and/or staff to facilitate response to clients, awareness of NPEP protocol, and improved communication re: NPEP and other treatment for client.

Information Sheet:

Create a patient/client information sheet that has contact information for the local MD, pharmacies that have the medications or can get them quickly, and for the *Rape Crisis Center. PROVIDE THIS TO CLIENTS, AS APPROPRIATE, AS PART OF THE ADVOCACY PROCESS.*

The Basics:

- Depending upon multiple factors, the victim/client may have been exposed to HIV. Although, the risk of actual infection is low (< 1% chance of contracting HIV – see table below), preventative treatment (NPEP – non-occupational post-exposure prophylaxis) may be appropriate.
- Clients who are HIV positive prior to the assault should not receive NPEP. If a client is given NPEP and the baseline HIV test is positive, the client will be advised to stop NPEP immediately.
- NPEP is most effective when provided immediately following the exposure. Effectiveness decreases significantly with the passing of each hour and is considered not at all effective after 72 hours.
- Recommended NPEP treatment is a 28 day regimen: Combivir and Kaletra. Other drugs are available and may be prescribed at the discretion of medical personnel. These drugs do have side effects, most commonly nausea and vomiting. Medical personnel can prescribe medication to counteract nausea.
- Clients will need to follow up with a primary care physician or infectious disease specialist for ongoing testing to insure that the medication isn't harming them. This will need to be done 3-5 days into the medication and repeated per physician guidance. Programs are encouraged to do a follow up call with clients to remind them of this need and to offer help making appointment with physician.
- Clients should also follow up with HIV testing at 1 month, 3 months, and 6 months after exposure. This should be noted on the information sheet provided to the client.
- Payment for NPEP is provided by the Crime Victims' Compensation Board. The hospital and/or pharmacy should directly bill the CVCB and never bill the client for this service.

Frequently Asked Questions:

What is the risk for exposure?

For clients, see table below – generally less than 1% based upon a single exposure. The risk to you, as an advocate, is very low. Advocates should always avoid exposure to any body fluids, particularly blood. Advocates should not handle medical equipment. If a client is bleeding excessively, medical care should be completed before the advocate is introduced to the client.

What is NPEP and Prophylaxis?

NPEP is Non-Occupational Post Exposure Prophylaxis. Prophylaxis is preventive treatment for a possible exposure – in this case, specific to exposure to the HIV anti-virus.

Why was prophylaxis not offered to my client?

There are many reasons NPEP may not be offered as treatment. Due to the complexity of treatment for HIV, there are concerns about medicating in any situation where the risk of re-exposure is high or the likelihood that the person will complete the medications is low. Also, the effectiveness is limited to a 72 hour time frame following exposure. This treatment is not appropriate for clients who are already HIV positive whether or not they are currently taking medication. Medical personnel will do a baseline test for HIV status.

Medical personnel will assess the appropriateness of NPEP to the individual based upon how much time has passed since the exposure (assault), the victim's expressed interest or willingness to complete the entire 28 day treatment, and/or the victim's current HIV status. See page 11 of this document for assessment guide.

Estimated Per-Act Risk for Acquisition of HIV

Exposure Route	Risk per 10,000 exposures
Blood Transfusion	9,000 (9 out of 10)
Needle-sharing injection drug use	67
Receptive anal intercourse	50
Percutaneous needle stick	30
Receptive penile-vaginal intercourse	10
Insertive penile-vaginal intercourse	5
Receptive oral intercourse	1
Insertive oral intercourse	0.5

What if my client doesn't want this treatment?

Clients may decline NPEP the same as any other part of treatment.

What are the side effects?

The recommended NPEP treatment is Kaletra and Combivir. The most common side effects of these drugs include nausea/vomiting, diarrhea, trouble sleeping, headache, tiredness, dizziness, or cough. Medical personnel can prescribe additional medication to help offset some of these side effects. It is important to support clients in determining for themselves whether or not the benefit of taking the full course of medication is greater than the suffering that side effects may cause.

What can I do as an advocate to help my client with this process?

Educate yourself regarding this protocol so that you may advocate for the best response for your client. As always, provide support and information for your client so that he/she may make the best decision for him/herself. And, as mentioned before, it is very important for the program to have some preliminary community work done to create the most responsive environment for a client.

CLINICAL INFRASTRUCTURE CONSIDERATIONS

When occupational PEP was first integrated into the healthcare system, significant resources were required in order to provide information to exposed individuals about the resources available to them, to educate healthcare providers to develop the expertise required to provide the service, to develop systems to provide rapid access to medications, and to provide follow-up services. Similar resources will be required in the non-occupational setting.

Unless a specific system is in place to respond to requests for NPEP, all healthcare systems will face the challenge of responding rapidly to this need in the context of a busy work environment. Healthcare providers and systems in local communities should work together to identify one or more sites where comprehensive NPEP services will be provided. Once a site or sites are identified, likely sources of entry (ie. emergency departments, urgent care centers, HIV clinics, public health clinics, advocacy centers, etc.) should be notified about how to make referrals. Initial assessment and treatment should be provided at the point of entry, with referral for comprehensive and ongoing care to the identified site or sites that provide NPEP services within a day or so.

Emergency Departments and Urgent Care Clinics

All emergency departments and urgent care clinics should work with local public health, STI, and/or HIV clinics to establish systems for the initial assessment and prescription of NPEP followed by rapid access (preferably the same day or next day, always within 3-5 days) to a provider for HIV counseling and testing and the provision of the remainder of the NPEP course (total of 28 days). NPEP can only be initiated up to 72 hours after potential exposure.

Private Infectious Disease Practices

Clinicians in HIV clinics are encouraged to integrate HIV patient education and testing, routine STI testing, hepatitis immunizations, etc., if not already a part of the normal resources in order to provide comprehensive NPEP services in this setting.

CLINICIAN TRAINING RESOURCES

The National AIDS Education and Training Centers (AETC) Program authorized by the Ryan White CARE Act supports eleven regional centers that conduct multidisciplinary education and training programs for health care providers treating persons with HIV/AIDS. AETC programs are administered by the Health Resources and Services Administration (HRSA), HIV/AIDS Bureau. AETC's focus is on training clinicians in Ryan White Part C funded clinics, such as physicians, advanced practice nurses, nurses, physician assistants, dental professionals and pharmacists. Training activities are based upon assessment. Emphasis is placed on interactive, hands-on training and clinical consultation. Below is the AETC Local Performance Site in Kentucky. The Center is available for training about NPEP as well as other HIV-related topics.

Kentucky AIDS Education Training Center
UK Chandler Medical Center, MN672
Lexington, KY 40536
(P) 866.777.9969
(F) 859.257.3477

The Part C Early Intervention Services Program is 1 of 5 programs federally funded under the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. The Part C program was created to provide outpatient, early-intervention primary care and support services to persons living with HIV/AIDS. The following services must be provided either on site or at another facility in the community: HIV counseling, testing, and referral, counseling and education on living with HIV disease, medical evaluation and clinical care, and oral health care, mental health care, outpatient substance abuse treatment, nutritional services, and specialty medical care directly or by referral. Below are the local Ryan White Clinics located in Kentucky, each covers a wide range of counties in it's area:

Henderson and Owensboro
Matthew 25 Aids Services
452 Old Corydon Road,
Henderson KY 42420
Referrals: 270.826.0200
And, 1600 Breckenridge Street,
Owensboro KY 42303

Louisville
WINGS
550 S Jackson St, 2nd Fl., ACB
Louisville, KY 40202
Referrals: 502.561.8844

Lexington
Bluegrass Care Clinic
5th Kentucky Clinic,
S. Limestone
Lexington, KY 40536
Referrals: 859.323.1688

Western Kentucky
Paducah
Heartland Care Clinic
630 N 30th St.
Paducah, KY 42001
Referrals: 270.444.8183

Sample Forms

Sample forms and/or policies are provided by way of example only and are not intended to replace or supplant hospital policy or guidance from the hospital legal team.

SEXUAL ASSAULT PATIENT
DISCHARGE INSTRUCTIONS

Medical Record No:
Name:
Date/Time:

As a part of your medical treatment, specimens may have been collected from you. If you consent to report to law enforcement, some or all of these specimens may be used as evidence. Your exam was completed by _____
Examiner Name/Title

Please review and make your primary doctor aware of the following, if necessary.

The following tests were conducted:

- ❑ Urine Pregnancy Test- Results: ❑Positive ❑Negative
- ❑ Urine Dip OR Urinalysis
- ❑ Blood Testing
- ❑ State Crime Lab Toxicology Kit
- ❑ HIV Test
- ❑ CBC and Comp (if given HIV medications)
- ❑ Hepatitis Panel
- ❑ Other Tests_____

- ❑ Syphilis
- ❑ Other
- ❑ Other_____
- ❑ Other_____

_____

Medications given or sent home with the patient:

Treatment for Gonnorhea

- ❑ Ceftriaxone (Rocephin) 250 mg IM x 1 dose OR
- ❑ Levofloxacin (Levaquin) 250mg PO x 1 dose

Treatment for Chlamydia

- ❑ Azithromycin (Zithromax) 1 gram PO x 1 dose OR
- ❑ Doxycycline 100mg PO twice a day for 7 days prescription

Treatment for Trichomoniasis

- ❑ Metronidazole (Flagyl) 2 grams PO x 1 dose

Post Coital Contraception

- ❑ Levonorgestrel (Plan B) 0.75 mg tablets: 1 tablet now and 1 tablet in 12 hours at _____

Treatment for Tetanus

- ❑ Tdap (ADACEL) 0.5ml IM x 1 dose OR
- ❑ Tetanus Toxoid 0.5 ml IM x 1 dose
- ❑ Hepatitis B vaccination (Recombivax HB) 0.5 ml IM x 1 dose - **Series #1**
  Series #2 due_____(1 month)
  Series #3 due_____(6 months)
- ❑ Promethazine (Phenergan) 25 mg PO x 1 dose
- ❑ HIV Prophylaxis—You were given a 7 days starter , to complete the full HIV prophylaxis you will need to follow-up in less than 7 days to receive counseling, blood tests and the remainder of the medication regiment to complete the 28 day dose.

-

_____
_____
_____

SEXUAL ASSAULT PATIENT
DISCHARGE INSTRUCTIONS

Medical Record No:
Name:
Date/Time:

Check mark only the following that apply:

- ❑ I understand when I have a follow-up examination (with my clinic/doctor of choice), I should bring this sheet, so that my health care provider will know what treatment I received and can perform tests to be sure that the medications were effective.
- ❑ I understand that I should refrain from alcohol in the next 48 hours because of the medications that were given to me.
- ❑ I understand that if I need to be vaccinated for Hepatitis B, it is given in a series of 3 injections and it is important that all shots in the series get completed to provide immunization.
- ❑ I understand that it is strongly recommended that I have a gynecological exam in 1 week with my clinic/doctor of choice and a repeat urine pregnancy test in 1 week.
- ❑ I understand that it is strongly recommended that I receive follow-up care of any genital/anal/oral injury every week until healed at my clinic/doctor of choice.
- ❑ I understand I should also report to my health care provider any unusual bleeding, vaginal or rectal discharge and/or pelvic pain and any other symptoms that may be related to the assault.
- ❑ I understand that if at any time in the next 2-3 days I experience severe pain, ongoing nausea or vomiting or any other unusual medical complaints that I have been advised to see my primary care physician or go to the nearest Emergency Department.
- ❑ I understand that it is strongly recommended that I receive follow-up care of any human bite mark injury every week until healed at my clinic/doctor of choice.

Safe Sex Education (ALL PATIENTS INITIAL HERE)

____ I have received education about and realize that I should practice safe sex with any sexual partner.

Emergency Contraception Pills (INITIAL HERE ONLY IF GIVEN EC)

____ I understand that emergency contraception pills use hormones to prevent the ovary from releasing an egg and also to prevent implantation of an egg in the uterus. All of these effects prevent pregnancy from occurring. This method is more than 89% effective in preventing implantation if taken within 72 hours of unprotected intercourse. If you decided to use this method, you received _____(write in medication given).

It is very important that you take these pills exactly as instructed. You may experience some nausea, vomiting, diarrhea, fatigue, headache, or breast tenderness. This is normal and will go away without treatment in 8-12 hours. You may also experience spotting, early/late period, or heavy/lighter period. It may take as long as 2 weeks for your period to start. You are to have a repeat urine pregnancy test in 1 week. If you do not start your period, or if you suspect that you are pregnant, you should go to your doctor immediately. If you have difficulty breathing, closing of your throat, swelling of your lips, tongue or face, or severe stomach tenderness, go to the nearest Emergency Department immediately or call 911.

HIV Risk (ALL PATIENTS INITIAL HERE)

____ I have received information regarding my risk for contracting HIV from this assault and about the FREE HIV testing I can receive. I understand that although rare, the HIV virus, which causes AIDS can be transmitted during a single sexual encounter. Follow-up blood HIV tests are recommended 6 weeks, 3 months and 6 months after the assault. This testing is performed at _____.

Phone #_____

(INITIAL HERE ONLY IF GIVEN HIV MEDICATION)

_____I understand that I should not drink alcohol while taking the HIV medications. I understand that I will need to be closely followed by named clinic_____Phone #_____ or by my primary doctor. I understand that to make the HIV medications most effective I will need to take the full 28-day regimen. I will have to follow-up per the doctor's recommendation to have repeat blood work performed and to receive the rest of the medications. With your consent, your healthcare provider has sent the above- mentioned clinic your information, so that they may contact you to set up your appointments. If you experience difficulty breathing, closing of your throat, swelling of your lips, tongue or face, severe stomach tenderness, uncontrolled vomiting, go to the nearest Emergency Department Immediately or call 911.

By signing below I realize I have received all marked information on this sheet and have had a chance to get all of my questions/concerns addressed prior to discharge.

_____ **Patient Signature**

_____ **Examiner or Nurses Signature**

SEXUAL ASSAULT PATIENT
NPEP DISCHARGE INSTRUCTIONS

Medical Record No:
Name:
Date/Time:

During my evaluation it was determined that I may have been exposed to the HIV virus from this sexual assault.

I have been given a choice to take a 28 day medicine regimen that may help prevent transmission of the HIV virus to me from this assault.

Completed Today	Initial	I NEED	Check Off
HIV Risk assessment		Primary or Infectious Disease physician	
Rapid HIV test		Confirmation HIV test	
Baseline blood tests			
7 day starter pack of medication		Repeat blood tests at 4 and 6 weeks, then again at 3 and 6 months	
Education of drug side effects		Screening tests and/or treatment for sexually transmitted infections, Hepatitis B and C	
Education of follow up instructions		Get Hepatitis A & B immunizations (if indicated)	
Education of symptoms of AIDS		Remaining 21 days of medication	
		To practice safe sex	

Step 1. Take **all** the medications given to you as directed

Step 2. You need to see a doctor within 7 days of your exam.
Contact your primary physician – schedule a follow up appointment.
If you do not have a primary physician contact an Infectious Disease physician in your area to schedule the appointment.

Make sure to tell the medical facility with whom you are trying to get an appointment that you are a victim of sexual assault and you have already started the NPEP medications and you must see a physician within 7 days of starting this medicine.

Step 3. Take this form along with your other discharge instructions to your physician

I, _____, after an explanation of all of the listed information in the above table, I choose to take the medications.

I, _____, after an explanation of all of the listed information in the above table, I choose NOT to take the medications.

Other Resources:
Kentucky HIV/AIDS Branch Hotline 1-800-420-7431
Kentucky Infectious Disease Consult 24/7 1-800-888-5533

SEXUAL ASSAULT PATIENT
FOLLOW-UP CARE
HIV Post Exposure
Prophylaxis (NPEP) Referral

Medical Record No:
Name:
Date/Time:

Date: _____/_____/_____
[MM] [DD] [YYYY]
Facility of SA Examination:
_____
Address:_____
Telephone #: ( ) _____ - _____

Name: _____
Pt. Acct. #:_____
DOB: _____/_____/_____
[MM] [DD] [YYYY]

Gender: _____ [M] _____ [F]

Exposure and HIV Information

Date of Exposure: _____/_____/_____
[MM] [DD] [YYYY]
Time of Exposure: _____ [AM / PM]

Hours Between Exposure & NPEP initiation:
_____

County and State Where Exposure Occurred:
_____

Exposure Description:
Describe: (including injury)
_____
_____
_____

***Source* HIV Status:**
❑ Reactive ❑ Nonreactive ❑ Unknown
***Source* ARV Medication History:**
❑ None ❑ Unknown ❑ Yes-Describe
_____

Previous HIV testing:
Date: _____/_____/_____
[MM] [DD] [YYYY]

Result of last HIV test:
❑Positive ❑Negative ❑Unsure ❑No Prior Testing

Other Exposures in past 6 months (# and type):
_____

Hepatitis status: A_____ **B**_____

Medical History

Pertinent Past Medical History:
_____
_____
_____
_____
_____
Drug Allergies: _____
Current Meds: _____
_____
_____

Assessment and Plan
Labs Completed:
Pregnancy Test: ❑ Positive ❑ Negative
❑ CBC ❑ Liver enzymes ❑ BUN/Cr.
❑ Rapid HIV
❑ Hepatitis serology

❑ **Reviewed with patient:** Drug information, adverse events, emergency phone numbers, medication adherence, use of alcohol.

❑ **Medication given/ RX** (please describe)
_____
_____
_____

❑ **Follow up appointment established with**
_____
for _____/_____/_____
[MM] [DD] [YYYY]

❑ **Referral and lab results faxed**

PATIENT INFORMATION SHEET

PREVENTION TREATMENT

What is NPEP?

- NPEP stands for "non-occupational Post-Exposure Prophylaxis (or Prevention)" which means after you've been exposed, this medication program may help prevent you from getting HIV
- NPEP may be useful up to 72 hours after exposure.
- The NPEP program includes HIV testing, a 28-day course of anti-HIV medication, and counseling and referrals to help you stay safe and HIV negative in the future.
- The medication provided is Combivir which is a combination of two HIV medications: AZT and 3TC, and Kaletra which is a combination of lopinavir and ritonavir.
  - o You should drink plenty of liquids with the pills.
  - o Common side effects of the drug are: tiredness, nausea, diarrhea, and headache. About half of the people who take this medication experience these and usually only for a few days. Taking medications with food may decrease nausea.
  - o There is some potential for more serious side effects – your healthcare provider should go over this information with you and detailed information will be provided with the prescription. Ask if you have any concerns.
  - o Note: Combivir may interfere with other HIV treatment regimen – please advise your healthcare provider if you have previously tested positive for HIV.

Does NPEP work?

- There is no direct evidence that NPEP works to prevent HIV transmission in sexual assault. However, there is related information that indicates that NPEP is partially effective.
- Healthcare workers who had needle sticks and received PEP had an 81% reduction in getting HIV compared to those who did not receive PEP.
- Infants born to HIV positive mothers had a significant reduction in acquiring HIV when given HIV medication to prevent transmission.
- NPEP will be most effective if you take all medications as prescribed by your healthcare provider. Take all medications in the dose prescribed and do not stop taking the medication without consulting your healthcare provider. Skipped/missed doses or stopping medication early may result in drug resistance meaning that HIV would be able to overcome a drug that used to work well to keep HIV from spreading.

What do I do next?

- It is important to receive follow-up HIV testing after you complete the 28 day course of medications.
- It is strongly suggested that you get a follow-up test at 6 weeks, 3 months and again at 6 months after exposure. This may be done with your primary care physician, an infectious disease specialist, or at the health department.
- If you have any questions or concerns, ask. Your healthcare provider can inform you about other resources that may be helpful including your local rape crisis center, counseling services, mental health support, substance abuse support, or other service providers.

What is my risk of contracting HIV?

Exposure Type	Chance of infection per each contact
Receptive anal intercourse	1-3%
Insertive anal intercourse	– 1%
Shared injection equipment (drug use)	.67% (<1%)
Receptive vaginal intercourse	0.1-1%
Insertive vaginal intercourse	<0.1%
Other potentially infectious body fluid on mucous membrane or wounded skin	<1%
Receptive oral intercourse w/ ejaculation into mouth	Unknown: statistically no risk, but there are a few reports of infection transmission

- The average risk of infection from one exposure is relatively small; but, there is no way to know the actual risk of a specific individual exposure.
- It is possible to get HIV from a single episode of unprotected sexual contact or shared injections
- The % risks listed above are very small – but, health care workers who get a needle stick have a risk of 0.3%. For those who get blood splashed in the mouth or eye, the risk is about 0.09%. PEP is potentially offered in both instances after considering factors associated with the exposure and the source patient.
- Your risk of infection increases if there were multiple types and times of penetration.
- Your risk of infection is directly proportionate to the likelihood of the perpetrator being infected with HIV. Your risk is increased if the perpetrator is considered in a high risk group (shares injection equipment with others, history of multiple partners with high risk including sex workers, etc.)

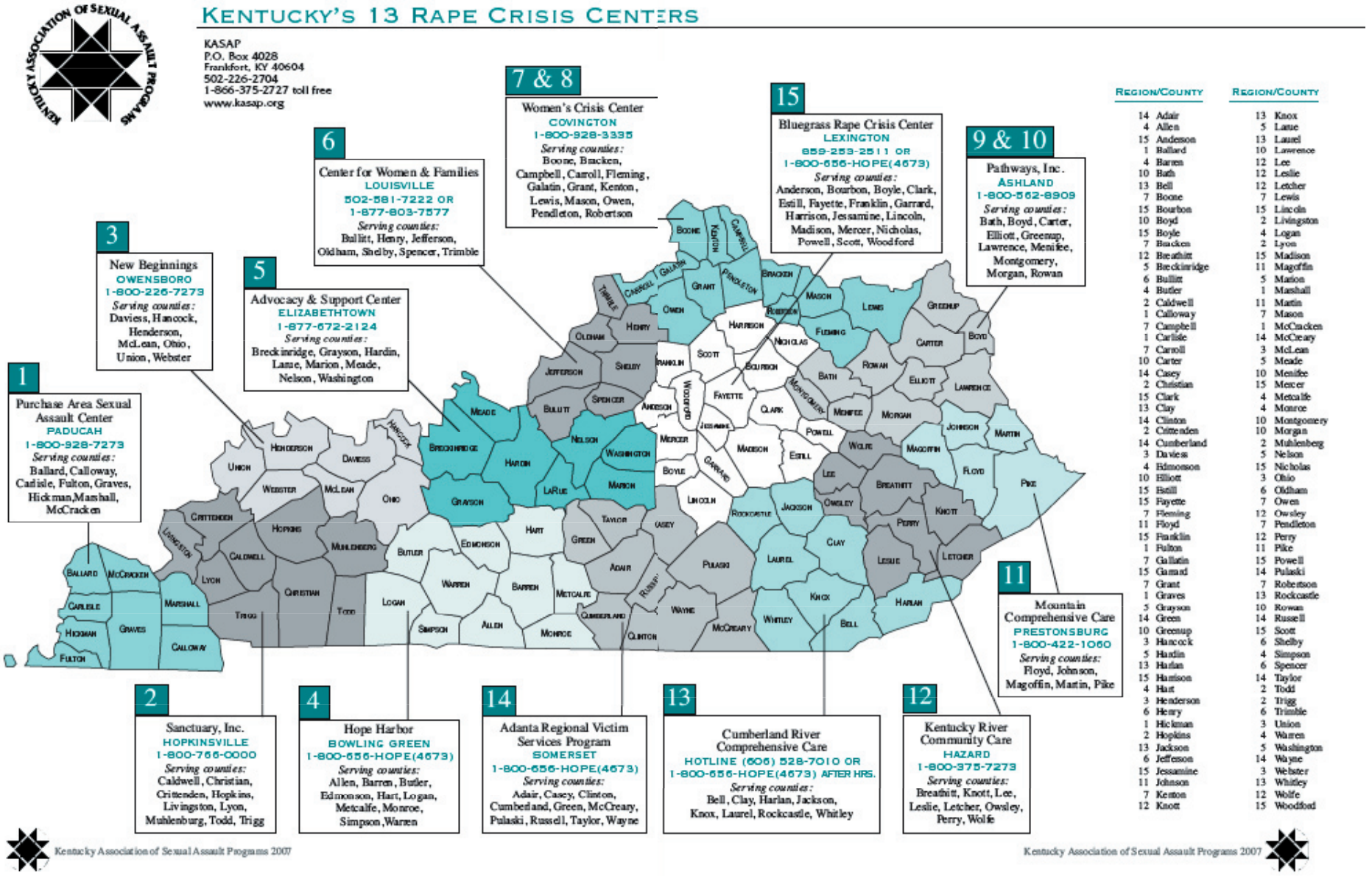
What can I do now that I may have been exposed to HIV?

- Immediately communicate with your healthcare provider about the types and numbers of possible exposures.
- Consider with your healthcare provider whether or not a medication program would benefit you (see next page re: NPEP).
- Tell your healthcare provider if you are on any medications – especially medications that treat HIV.

What if I am already HIV positive?

- It is important for you to know if you are already HIV positive before making the decision to take preventative (NPEP) medications.
- You will be given an HIV test and a starter pack of medication. If your initial HIV test is positive, you must stop NPEP medication because it will not benefit you and may harm you. An initial positive test indicates that HIV transmission has occurred from a previous exposure.
- If you know you are HIV positive, tell your healthcare provider so that you can receive appropriate treatment.

MAP OF RAPE CRISIS CENTERS IN KENTUCKY



Region	County
14	Adair
4	Allen
15	Anderson
1	Ballard
4	Barren
10	Bath
13	Bell
7	Boone
15	Bourbon
10	Boyd
15	Boyle
7	Bracken
12	Breathitt
5	Breckinridge
6	Bullitt
4	Butler
2	Caldwell
1	Calloway
7	Campbell
1	Carlisle
7	Carroll
10	Carter
14	Casey
2	Christian
15	Clark
13	Clay
14	Clinton
2	Crittenden
14	Cumberland
3	Daviess
4	Edmonson
10	Elliott
15	Estill
15	Fayette
7	Fleming
11	Floyd
15	Franklin
1	Fulton
7	Gallatin
15	Garrard
7	Grant
1	Graves
5	Grayson
14	Green
10	Greenup
3	Hancock
5	Hardin
13	Harlan
15	Harrison
4	Hart
3	Henderson
6	Henry
1	Hickman
2	Hopkins
13	Jackson
6	Jefferson
15	Jessamine
11	Johnson
7	Kenton
12	Knott

Region	County
13	Knox
5	Larue
13	Laurel
10	Lawrence
12	Lee
12	Leslie
12	Letcher
7	Lewis
15	Lincoln
2	Livingston
4	Logan
2	Lyon
15	Madison
11	Magoffin
5	Marion
1	Marshall
11	Martin
7	Mason
1	McCracken
14	McCreary
3	McLean
5	Meade
10	Menifee
15	Mercer
4	Metcalfe
4	Monroe
10	Montgomery
10	Morgan
2	Muhlenberg
5	Nelson
15	Nicholas
3	Ohio
6	Oldham
7	Owen
12	Owsley
7	Pendleton
12	Perry
11	Pike
15	Powell
14	Pulaski
7	Robertson
13	Rockcastle
10	Rowan
14	Russell
15	Scott
6	Shelby
4	Simpson
6	Spencer
14	Taylor
2	Todd
2	Trigg
6	Trimble
3	Union
4	Warren
5	Washington
14	Wayne
3	Webster
13	Whitley
12	Wolfe
15	Woodford

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PATIENT INFORMATION SHEET

PREVENTION TREATMENT

What is NPEP?

- NPEP stands for "non-occupational Post-Exposure Prophylaxis (or Prevention)" which means after you've been exposed, this medication program may help prevent you from getting HIV
- NPEP may be useful up to 72 hours after exposure.
- The NPEP program includes HIV testing, a 28-day course of anti-HIV medication, and counseling and referrals to help you stay safe and HIV negative in the future.
- The medication provided is Combivir which is a combination of two HIV medications: AZT and 3TC, and Kaletra which is a combination of lopinavir and ritonavir.
  - o You should drink plenty of liquids with the pills.
  - o Common side effects of the drug are: tiredness, nausea, diarrhea, and headache. About half of the people who take this medication experience these and usually only for a few days. Taking medications with food may decrease nausea.
  - o There is some potential for more serious side effects – your healthcare provider should go over this information with you and detailed information will be provided with the prescription. Ask if you have any concerns.
  - o Note: Combivir may interfere with other HIV treatment regimen – please advise your healthcare provider if you have previously tested positive for HIV.

Does NPEP work?

- There is no direct evidence that NPEP works to prevent HIV transmission in sexual assault. However, there is related information that indicates that NPEP is partially effective.
- Healthcare workers who had needle sticks and received PEP had an 81% reduction in getting HIV compared to those who did not receive PEP.
- Infants born to HIV positive mothers had a significant reduction in acquiring HIV when given HIV medication to prevent transmission.
- NPEP will be most effective if you take all medications as prescribed by your healthcare provider. Take all medications in the dose prescribed and do not stop taking the medication without consulting your healthcare provider. Skipped/missed doses or stopping medication early may result in drug resistance meaning that HIV would be able to overcome a drug that used to work well to keep HIV from spreading.

What do I do next?

- It is important to receive follow-up HIV testing after you complete the 28 day course of medications.
- It is strongly suggested that you get a follow-up test at 6 weeks, 3 months and again at 6 months after exposure. This may be done with your primary care physician, an infectious disease specialist, or at the health department.
- If you have any questions or concerns, ask. Your healthcare provider can inform you about other resources that may be helpful including your local rape crisis center, counseling services, mental health support, substance abuse support, or other service providers.

What is my risk of contracting HIV?

Exposure Type	Chance of infection per each contact
Receptive anal intercourse	1-3%
Insertive anal intercourse	– 1%
Shared injection equipment (drug use)	.67% (<1%)
Receptive vaginal intercourse	0.1-1%
Insertive vaginal intercourse	<0.1%
Other potentially infectious body fluid on mucous membrane or wounded skin	<1%
Receptive oral intercourse w/ ejaculation into mouth	Unknown: statistically no risk, but there are a few reports of infection transmission

- The average risk of infection from one exposure is relatively small; but, there is no way to know the actual risk of a specific individual exposure.
- It is possible to get HIV from a single episode of unprotected sexual contact or shared injections
- The % risks listed above are very small – but, health care workers who get a needle stick have a risk of 0.3%. For those who get blood splashed in the mouth or eye, the risk is about 0.09%. PEP is potentially offered in both instances after considering factors associated with the exposure and the source patient.
- Your risk of infection increases if there were multiple types and times of penetration.
- Your risk of infection is directly proportionate to the likelihood of the perpetrator being infected with HIV. Your risk is increased if the perpetrator is considered in a high risk group (shares injection equipment with others, history of multiple partners with high risk including sex workers, etc.)

What can I do now that I may have been exposed to HIV?

- Immediately communicate with your healthcare provider about the types and numbers of possible exposures.
- Consider with your healthcare provider whether or not a medication program would benefit you (see next page re: NPEP).
- Tell your healthcare provider if you are on any medications – especially medications that treat HIV.

What if I am already HIV positive?

- It is important for you to know if you are already HIV positive before making the decision to take preventative (NPEP) medications.
- You will be given an HIV test and a starter pack of medication. If your initial HIV test is positive, you must stop NPEP medication because it will not benefit you and may harm you. An initial positive test indicates that HIV transmission has occurred from a previous exposure.
- If you know you are HIV positive, tell your healthcare provider so that you can receive appropriate treatment.