# MEDICAL GUIDELINES

## FOR HIV POST-EXPOSURE PROPHYLAXIS (HIV PEP)

### FOR SEXUAL ASSAULT VICTIMS/SURVIVORS

## 1. MEDICAL GUIDELINES – HIV PEP STARTER KIT

**Ontario SA/DVTC Medical Guidelines for Administering HIV Post-Exposure Prophylaxis Starter Kit in Cases of Sexual Assault Medical Guideline Practice Components**

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## MEDICAL GUIDELINES – HIV PEP FOLLOW UP

**Ontario SA/DVTC Medical Guidelines for Administration of Follow-up Doses of HIV Post-exposure Prophylaxis**

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**April 2003**

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BACKGROUND:

- HIV PEP is recommended to prevent transmission of HIV following occupational and non-occupational exposures such as unprotected sexual activities and injection drug use. It consists of a combination of drugs that are given together for a duration of 28 days. The specific combination depends on the age of the victim/survivor, whether they are taking other medications already and the pregnancy status.

- The antiretroviral agents used for HIV PEP are tenofovir/emtricitabine (Truvada®), lopinavir/ritonavir (Kaletra®), raltegravir (Isentress®), zidovudine/lamivudine (Combivir®), lamivudine (3TC®) and zidovudine (Retrovir®). This modification is based on expert opinion and takes into consideration the favourable tolerability profile of Tenofovir/emtricitabine in comparison to the previously recommended antiretroviral regimens for pregnant women and children < 12 years old, < 35 kg or unable to swallow tablets. Insufficient data in pregnant women and children < 12 years old, < 35 kg precludes the use of Tenofovir/emtricitabine in these populations.

- Three different regimens are suggested for different populations:
  - Non-pregnant Adults and Children ≥ 12 years old and > 35 kg:
    - Tenofovir/emtricitabine (Truvada®) and lopinavir/ritonavir (Kaletra®)
      - Lopinavir/ritonavir (Kaletra®) may be replaced by raltegravir (Isentress®) if possible drug interactions are present in clients ≥ 16 years old
  - Pregnant Women:
    - Zidovudine/lamivudine (Combivir®) and lopinavir/ritonavir (Kaletra®)
  - Children < 12 years old, < 35 kg or unable to swallow tablets:
    - Lamivudine/zidovudine (Combivir®) and lopinavir/ritonavir (Kaletra®)

- The Ministry of Health and Long-Term Care endorses this program and funds HIV PEP medications for all at-risk sexual assault victims/survivors receiving care at any of Ontario’s 35 SA/DVTCs.

- Heterosexual transmission has been stable since 2005 (20% of new infections in Canada, 2008).

- Women are twice as likely as men to contract HIV during (vaginal) intercourse. 39% of Canadian women have experienced at least one incident of sexual assault since the age of 16.

- Fear of HIV infection is common among sexual assault victims/survivors post-assault.


 PURPOSE:
To provide a guide to Registered Nurses (RNs) and Medical Doctors (MDs) in Ontario on the management of the baseline visit and on administering the 5-day HIV post-exposure prophylaxis (HIV PEP) starter kit to sexual assault victims/survivors.
Under medical directives and using this guideline, RNs will carry out sexual assault-related management, counselling, laboratory testing, HIV testing and arrange for follow-up as well as to provide the 5 day HIV PEP starter kit. When medical directives are not utilized, the ER physician will write an order for the five day HIV PEP starter kit which will be provided by the SADVTC program.

Each SA/DVTC program is linked with an HIV expert whom they can contact or consult with for any HIV-related issues.

USE:
HIV PEP is used to decrease the risk of transmission of HIV after sexual assault. In non-pregnant adults and children ≥ 12 years old and ≥ 35 kg it consists of a 28-day course of tenofovir/emtricitabine and lopinavir/ritonavir. If lopinavir/ritonavir cannot be given due to a possible drug interaction, raltegravir should be given instead if the client is ≥ 16 years old.

Tenofovir/emtricitabine should be avoided during pregnancy and in children under 12 years old or under 35 kg due to possible increased bone toxicity and lack of safety/efficacy data in these populations. Also, tenofovir/emtricitabine is not available in liquid formulation.

In pregnant women, HIV PEP consists of a 28-day course of zidovudine/lamivudine and lopinavir/ritonavir. In children less than 12 years old, under 35 kg or unable to swallow tablets, zidovudine/lamivudine and lopinavir/ritonavir should be given for a 28-day course. These agents are available both in tablet and liquid formulation.

At the initial visit, a sexual assault victim/survivor assessed to be at risk of HIV acquisition will be offered a 5-day starter kit. The initial dose is to be taken immediately, unless health and/or drug contraindications are present (see Appendix 1E). In the case of contraindications to lopinavir/ritonavir, administration of tenofovir/emtricitabine and raltegravir is recommended until appropriate bloodwork can be completed in clients ≥ 16 years old. Considering the speed at which HIV replicates in the human body, HIV PEP must be started as soon as possible post-assault to maximize its effectiveness. HIV PEP is not recommended if more than 72 hours have passed since the assault (exposure).

DOSAGE:

<table>
<thead>
<tr>
<th>NON-PREGNANT ADULTS, CHILDREN ≥12 YEARS OLD AND ≥ 35 KG:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tenofovir/emtricitabine 300/200 mg 1 tablet once a day x 5 days</td>
</tr>
<tr>
<td>Lopinavir/ritonavir 200/50 mg 2 tablets twice a day x 5 days</td>
</tr>
<tr>
<td>If lopinavir/ritonavir is contraindicated due to drug interaction and age ≥ 16 years old, replace with:</td>
</tr>
<tr>
<td>Raltegravir 400 mg 1 tablet twice a day x 5 days</td>
</tr>
</tbody>
</table>

Trade names of antiretroviral agents:

Tenofovir/emtricitabine: Truvada®
Zidovudine/lamivudine: Combivir®
Lamivudine: 3TC®
Lopinavir/ritonavir: Kaletra®
Raltegravir: Isentress®
Zidovudine: Retrovir®

December 3, 2011
PREGNANCY:
Zidovudine/lamivudine 300/150 mg 1 tablet twice a day x 5 days
Lopinavir/ritonavir 200/50 mg 2 tablets twice a day x 5 days

PAEDIATRIC MEDICATIONS (<12 YEARS OLD OR < 35 KG OR UNABLE TO SWALLOW TABLETS):
Zidovudine/lamivudine, lopinavir/ritonavir Dose according to weight

The medication may be taken together at the same time and can be taken with or without food.

INDICATIONS:
To be initiated within 72 hours post-assault with any victim/survivor of sexual assault if one of the following applies:
- Vaginal, anal or oral penetration with a penis has occurred, regardless of condom use or ejaculation
- The victim/survivor does not remember the sexual assault (e.g. drug-assisted).

CONTRAINDICATIONS/DRUG INTERACTIONS:
The RN must take a complete medication history including prescription drugs, over the counter medications, natural/herbal therapies, vitamins and recreational drug use. A health history must also be taken including kidney, liver, pancreatic and blood diseases to identify potential precautions or contraindications to HIV PEP.

All clients who accept HIV PEP must have baseline bloodwork done (Complete Blood Count, blood glucose, creatinine, AST, ALT, ALP, total bilirubin, WBC and differential, amylase, HIV and β-HCG (for women)). Clients with a history of chronic kidney or liver disease require additional baseline hepatic function tests (i.e., albumin, INR, PT, and PTT). The following tests are recommended: HIV, Hepatitis C Ab, Hepatitis B Ab and Ag, and VDRL. A history of hepatitis (including chronic hepatitis B or hepatitis C infection) does not automatically rule out the use of HIV PEP. However, in the event of acute symptomatic illness or severely elevated liver enzymes (> 5X upper limit of normal), HIV PEP use may be contraindicated, or dosage adjustments may be necessary. The RN should consult an MD, who then may want to consult an HIV specialist.

**Tenoforvir/emtricitabine** is not indicated and should be avoided in clients who have a creatinine clearance ≤ 30 mL/min or are receiving hemodialysis. **Tenoforvir/emtricitabine** should also be avoided in children < 12 years old or < 35 kg and in women during pregnancy.

**Raltegravir** is not indicated and should be avoided in children < 16 years old.

**Zidovudine/lamivudine and zidovudine** should be avoided in clients who have:
- Taken myelosuppressive or hemotoxic drugs within two weeks of starting HIV PEP drugs;
- A history of bone marrow insufficiency or severe anemia; and/or
- Acute pancreatitis

See Appendix 1E for a list of all contraindicated medications
The use of tenofovir/emtricitabine is not recommended in children < 12 years old or < 35 kg and in pregnant women due to the risk of bone toxicity. Some studies in children have shown a decrease in bone mineral density. At this time, data are considered insufficient to recommend the use of tenofovir/emtricitabine in children < 12 years old in whom the risk of bone toxicity may be greatest. Tenofovir/emtricitabine should also be avoided during pregnancy as animal studies have shown an increased risk of bone toxicity to the foetus when given at elevated doses and safety data in pregnant women are lacking.

Lopinavir/ritonavir interacts with many different drugs by affecting the liver cytochrome P450 drug metabolizing enzymes (see Appendix 1E as a quick reference). If the client is on any of these medications and is ≥ 16 years old, Raltegravir should be given instead of lopinavir/ritonavir. The use of raltegravir in children < 16 years old has not been sufficiently studied and should be avoided until more data is available. If the RN has any concerns about interactions with any other drug, give one dose of tenofovir/emtricitabine and raltegravir then contact a MD or pharmacist for verification.

As lopinavir/ritonavir can decrease the effectiveness of long-term use birth control pills, women requiring HIV PEP should be counselled regarding this and a barrier form of contraceptive (e.g., condom) should be strongly recommended. This should also be recommended during the testing period of sexually transmitted infection to decrease the possibility of transmission to sexual partners.

Non-essential medications (e.g. medications for erectile dysfunction) and complementary/alternative therapies including vitamins and herbal products should be discontinued during HIV PEP. Recreational drug use should also be discontinued for the duration of the HIV PEP regimen. Clients known to use recreational drugs regularly should be referred for counselling and treatment to increase the likelihood of adherence to HIV PEP.

The use of zidovudine/lamivudine and lopinavir/ritonavir during pregnancy has not been extensively studied. Nonetheless, this is the most frequently used antiretroviral regimen in pregnant women living with HIV and it is the regimen of choice based on efficacy studies completed in adults and clinical experience during pregnancy. Antiretroviral drugs are often avoided in the first trimester due to general concerns of teratogenesis. However, if the assailant is known to be HIV-positive or has HIV risk factors, the risk of HIV transmission outweighs the risk of teratogenesis, and HIV PEP should be given. If the client is pregnant, the RN is advised to consult an MD, who may wish to consult an HIV expert.

If the client is <12 years old or < 35 kg, the RN is advised to consult an HIV paediatrician after the 1st dose of zidovudine/lamivudine and lopinavir/ritonavir has been given.

Severe, potentially life-threatening, and fatal skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN) have been reported with raltegravir. Hypersensitivity reactions have also been reported and were characterized by rash, constitutional findings, and sometimes, organ dysfunction, including hepatic failure. Discontinue raltegravir and other suspect agents immediately if signs or symptoms of severe skin reactions or hypersensitivity reactions develop (including, but not limited to, severe rash or rash accompanied by fever, general malaise, fatigue, muscle or joint aches, blisters, oral lesions, conjunctivitis, facial edema, hepatitis, eosinophilia, angioedema). Clinical status including liver aminotransferases should be monitored and appropriate therapy initiated.

Trade names of antiretroviral agents: December 3, 2011
Tenofovir/emtricitabine: Truvada® Lopinavir/ritonavir: Kaletra®
Zidovudine/lamivudine: Combivir® Raltegravir: Isentress®
Lamivudine: 3TC® Zidovudine: Retrovir®
MEDICAL GUIDELINE PRACTICE COMPONENTS:

IMMEDIATE CARE FOR ALL CLIENTS
1. Acute medical needs of clients must always take precedence over the discussion of HIV PEP.
2. Determine time elapsed since the assault. If more than 72 hours have passed since the potential exposure, HIV PEP should not be offered.
3. Carry out the HIV Risk Assessment to determine whether the victim/survivor is at risk of HIV transmission. All at-risk victims/survivors are eligible to be offered HIV PEP. (See Appendices 1A & 1B).

FOR CLIENTS PRESENTING > 72 HOURS POST-EXPOSURE
4. If more than 72 hours have passed and the client is deemed at no risk of HIV transmission (no penetration and/or no contact with assailant body fluid), review the HIV Risk Pamphlet with them. Reassure them that they are at no risk, that HIV PEP is not recommended and that no follow-up for HIV is required. All other sexual assault-related follow-up is done as per the usual routine.
5. If more than 72 hours have passed and the client is deemed at risk:
   I. If the assailant is known to be HIV-positive, consult with an MD and/or an HIV specialist.
   II. For all other clients assessed as at risk of HIV exposure, recommend a baseline HIV test. If the client consents, draw blood for immediate testing or for storage for 7 months for future testing (where storage is possible). For immediate HIV tests, write “STAT” on the requisition. Review content of HIV Risk Assessment pamphlet and recommend follow-up HIV testing at 4-6 weeks, and 3 months post-assault.
   III. If client is taking HIV PEP then HIV testing should be repeated 6 months after the assault.

FOR CLIENTS PRESENTING < 72 HOURS POST-EXPOSURE
6. If the assailant is known to be HIV-positive, offer the client the first dose of HIV PEP immediately. Explain that due to the speed at which HIV replicates in the body, starting the medication as soon as possible greatly increases its efficacy. A delay in initiating HIV PEP reduces the effectiveness in this high-risk situation. An HIV expert should be contacted as soon as possible during working hours for a consultation. If the victim/survivor is < 12 years old or < 35 kg, a paediatric HIV expert should be contacted immediately.

If the client is at any risk of HIV acquisition, the RN and/or MD should consider offering the first dose of HIV PEP immediately due to the speed at which HIV replicates in the body. Delayed initiation of HIV PEP reduces its effectiveness at preventing HIV infection. The entire routine sexual assault procedure can take several hours, and may be too long to wait to start HIV PEP. Briefly discuss HIV risks and options for treatment with the client. It is at the RN’s discretion whether to provide in-depth information about the risks of HIV and HIV PEP at this time, or to wait until after completion of the Sexual Assault Evidence Kit. Timing of this discussion will be dependent on the situation (e.g. anxiety of client about HIV, urgency of completing Kit).

A single dose of tenofovir/emtricitabine, lopinavir/ritonavir, zidovudine/lamivudine and/or raltegravir is unlikely to cause negative health consequences even when contraindicated. Nonetheless, in cases in which there is significant concern about health contraindications or drug interactions of the HIV PEP regimen, consider providing only tenofovir/emtricitabine (or
zidovudine/lamivudine in case of pregnancy, age < 12 years or weight < 35 kg) at the initial dose until a proper medical/health history, bloodwork, consultation and counselling can be completed.

7. All other routine procedures carried out for sexual assault (including evidence collection) that the client chooses should be provided and completed. Complete all other routine sexual assault procedures (including evidence collection) that the client consents to.

8. To support the client in understanding HIV risks and in decision-making regarding HIV PEP, counsel the client regarding risks of HIV transmission, reviewing the *HIV Risk Assessment Pamphlet*.

**FOR CLIENTS AT NO RISK OF HIV ACQUISITION**

9. For clients assessed as at no risk of HIV acquisition, reassure the client that they are not at risk of HIV acquisition. Indicate that HIV PEP is not recommended and that no follow-up for HIV is required. All other sexual assault-related follow-up is done as per the usual routine.

**FOR CLIENTS AT-RISK OF HIV ACQUISITION**

10. Discuss the client’s degree of risk of contracting HIV and explain the drug regimen, including duration of treatment, follow-up process, side effects and efficacy of the combination therapy used in HIV PEP. See *HIV Risk Assessment Pamphlet*.

11. Take a complete medication history including prescription drugs, over the counter medications, natural/herbal therapies, vitamins and recreational drug use to identify potential precautions or contraindications to HIV PEP. (See Appendix 1E).

12. Take a health history including kidney, liver, pancreatic and blood diseases to identify potential precautions or contraindications to HIV PEP. (See Appendix 1E)

13. Determine if the client is pregnant. If she is pregnant, inform the MD immediately and consult the HIV expert as soon as possible during working hours (*but* still offer HIV PEP to clients determined to be at increased risk). See *Note to RNs and MDs at end of this section*.

14. If the client is < 12 years old or < 35 kg, inform the MD immediately and consult a paediatric HIV expert as soon as possible.

15. Determine if an HIV expert should be consulted (*see Appendix 1F*).

**FOR AT-RISK CLIENTS WHO DECLINE HIV PEP**

16. Review HIV follow-up information in *HIV Risk Assessment Pamphlet*.

17. Recommend taking a baseline blood sample for storage, for potential future HIV testing if a client’s follow-up test is HIV-positive. There are several options:

   I. The HIV testing can be done at this first visit; or

   II. Blood can be drawn for storage should a future HIV test be required (*see Appendix 1G*); or

   III. No HIV test if storage is not possible at your SA/DVTC.
Ontario Public Health Laboratories will expedite HIV test results if “STAT” is written on the requisition.

18. Review with the client that s/he should have follow-up HIV testing at 4-6 weeks and at 3 months after the assault.

19. Baseline HIV test results should be provided in person during subsequent follow-up visits. If an HIV test result is positive, the client should be phoned to make an appointment for post HIV test counselling and HIV test result disclosure with the follow-up RN.

20. Inform the client that over the next few months that s/he will need to protect her/his sexual partner(s) and provide counselling on how to do this. While waiting for the test results, the client should be counselled to take the following precautions to prevent potential transmissions to others:
   ◆ Use a latex condom with water based lubricant (or a dental dam for cunnilingus), or abstain from sex
   ◆ Do not donate blood, plasma, organs, tissue or sperm
   ◆ Do not share toothbrushes, razors, needles or other implements, which may have blood/body fluids on them.

FOR AT-RISK CLIENTS WHO ACCEPT HIV PEP

21. Determine appropriate drug regimen and dosages for the client:
   ◆ If the client is < 12 years of age or < 35 kg consult a MD.
     ● The MD should determine the doses of zidovudine/lamivudine and lopinavir/ritonavir using the Paediatric HIV PEP Dosage Charts (see Appendix 1D). The MD should consult a paediatric HIV expert and may also want to consult a pharmacist with expertise in this area.
   ◆ If the client is ≥ 12 years of age and ≥ 35 kg
     ● give her/ him the 5-day adult dose of the STARTER KIT: Tenofovir/emtricitabine 1 pill orally once a day for 5 days (5 pills total; 4 pills if first dose already given);
     ● lopinavir/ritonavir 2 tablets orally twice a day for 5 days (20 tablets total; 18 tablets if first dose already given)
   ◆ If the client is pregnant,
     ● give her the 5-day adult dose of the STARTER KIT:
     ● zidovudine/lamivudine 1 pill orally twice a day for 5 days (10 pills total; 9 pills if first dose already given); lopinavir/ritonavir 2 tablets orally twice a day for 5 days (20 tablets total; 18 tablets if first dose already given)

22. Review the HIV PEP Information Booklet sections summarizing the medications and the follow-up process in detail. Ensure that the client understands how to take the drugs, is aware of the possible side effects, and understands the process to follow if side effects are experienced.

23. Obtain specimens for complete blood count, blood glucose, creatinine, AST, ALT, ALP, total bilirubin, WBC and differential, amylase, HIV and STAT β-HCG (for women). Clients with a history of chronic kidney or liver disease require additional baseline hepatic function tests (i.e.,
albumin, INR, PT, and PTT). The following tests are recommended: Hepatitis C Ab, Hepatitis B Ab and Ag, and VDRL.

24. A baseline HIV test should be done on day 0 – 4. There are several options:
   • Blood can be drawn for storage to carry out an HIV test at day 2 – 4 after pre-test counselling is carried out (See Appendix 1G) or
   • The HIV test can be done at this first visit or
   • The HIV test can be done at days 2 – 4 if storage of blood is not possible at your SA/DVTC. This option requires an additional blood draw.

Ontario Public Health Laboratories will expedite HIV test results if “STAT” is written on the requisition.

25. Arrange for follow-up in 2-4 days and explain the follow-up procedures to the client (week 1 by phone, and week 2, 3 and 4 in person). See Medical Guidelines – HIV PEP Follow-up Care.

26. Review with the client that s/he should have follow-up HIV testing at 4-6 weeks, 3 and 6 months after the assault.

27. Other issues related to HIV PEP that the RN should inform clients of:
   • For the month that the client is taking the medications, s/he should use barrier precautions (e.g., condom) to avoid pregnancy and to prevent possible transmission of sexually transmitted infections to sexual partners.
   • Breastfeeding should be discontinued while on antiretroviral drugs. If suspicion of HIV infection is high enough to start therapy, then breast-feeding should be discontinued. HIV transmission from breast milk increases risk of infection to the baby by 14%. Consultation and/or referral to an adult or paediatric HIV expert for further discussion and counselling is recommended.
   • Lopinavir/ritonavir interferes with the action of the birth control pill. If the client is taking hormonal contraceptives in oral, patch, or vaginal ring formulations, advise her to use additional barrier forms of protection (e.g., condom) to prevent pregnancy while taking lopinavir/ritonavir, and up to 2 months after completing lopinavir/ritonavir.
   • Lopinavir/ritonavir does not interfere with the actions of short-course emergency contraceptives such as levonorgestrel (Plan B®) and Ovral®.
   • The client should notify the RN immediately if symptoms of rash develop, with or without constitutional symptoms such as fever, malaise, fatigue, muscle or joint aches, oral lesions, conjunctivitis, facial edema, and angioedema.

Note to RNs and MDs - Pregnancy: Antiretroviral drugs are potentially teratogenetic in the first trimester of pregnancy and are therefore often avoided during this period. However, if a woman is at high risk of seroconversion after a sexual assault, the risk of transmission to the fetus is very high due to the high viral load during the acute seroconversion phase of the disease. Therefore, giving antiretroviral drugs in this scenario is more important than the risk of teratogenesis.

Additional Note: If tenofovir/emtricitabine and/or lopinavir/ritonavir are contraindicated, alternate regimens will be covered with the MOHLTC funding.
Appendix 1A

Table 1: Risk Assessment for HIV Post-Exposure Prophylaxis (HIV PEP)

1. Determine HIV PEP Eligibility

<table>
<thead>
<tr>
<th>No Risk</th>
<th>At Risk</th>
</tr>
</thead>
</table>
| • NO penetration (anal, oral, vaginal)  
• NO contact with assailant body fluid (i.e. blood, ejaculate) | + ANY Assailant | NO penetration (Suspected, partial or completed)  
VAGINAL penetration (Suspected, partial or completed)  
ORAL penetration (Suspected, partial or completed)  
Contact with assailant body fluid (i.e. blood, ejaculate)  
• Via mucosa membrane, non-intact skin or bite  
• Unknown exposure (i.e. drug-assisted) + ANY Assailant |

DO NOT Offer HIV PEP  
Offer HIV PEP  
Provide counselling and education

2. Weigh Client HIV Risks (case by case assessment)

Two sets of factors must be considered when assessing HIV risk:

a) Exposure Risk Factors

- Anal penetration (suspected, partial or completed)
- Vaginal penetration (suspected, partial or completed)
- Anal, vaginal or oral injuries
- Blood in the anus, vagina or mouth
- Presence of sexually transmitted infections
- Presences of ulceration (open sores) on the genitals
- Assault by multiple assailants
- Multiple receptive sites
- Oral penetration only (NO vaginal OR anal penetration)
- Contact with assailant body fluid only (i.e. blood, ejaculate)
- Via mucous membrane, non-intact skin or bite
- No ejaculation
- Condom Use

If any of these factors were present during the assault, HIV risk is INCREASED

These factors may DECREASE HIV risk

b) Assailant Risk Factors

Assailant know to be HIV-positive
Assailant know or suspected to have HIV risk factors

HIV Risk Factors:

- Has Hepatitis C
- Intravenous drug user
- Man who has sex with men
- From a country with an HIV prevalence rate greater than 5% (i.e. certain countries in Sub-Saharan Africa)
- Has numerous sexual partners
- Has a sexually transmitted infection
- Engages in prostitution or trades sex for money/drugs
- Has sex with known or suspected HIV-positive people
- Has prior convictions for sexual assault
- Has been in prison

IF any of these factors are known or suspected, HIV risk is INCREASED

NOTE: These factors are often difficult to assess in cases of sexual assault, as victims/survivors may not know if the assailant ejaculated or whether condoms were used properly or at all. Therefore, caution should be used when considering them in the risk assessment. Unless no penetration occurs, these factors only decrease the risk and do not make it zero.
Although Table 1 assists the health care provider in determining whether to offer HIV PEP, the client may still be anxious and need more information about the risk of transmission to formulate a realistic sense of her/his individual risk. It is important for the client to understand their risk as it is ultimately her/his decision to take the prophylactic medication. It is the health care provider’s responsibility to inform the client of the possible risk, options and recommendations to allow her/him to evaluate the risks and benefits of taking HIV PEP.

Per incident probabilities of transmission when the assailant is known to be HIV-positive may be helpful in assisting the client with her or his decision-making:

**Table 2: Per incident probabilities of HIV Transmission, various exposure types**

<table>
<thead>
<tr>
<th>EXPOSURE TYPE</th>
<th>RISK OF HIV TRANSMISSION (HIV-positive source)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Sexual Transmission</td>
<td></td>
</tr>
<tr>
<td>Blood Product</td>
<td>1:1.1 (90%)</td>
</tr>
<tr>
<td>Needleshaing in IV drug use</td>
<td>1:159 (0.67%)</td>
</tr>
<tr>
<td>Needlestick injury</td>
<td>1:300 (0.3%)</td>
</tr>
<tr>
<td>Sexual Transmission (unprotected)</td>
<td></td>
</tr>
<tr>
<td>Receptive anal intercourse</td>
<td>1:200 (0.5%)</td>
</tr>
<tr>
<td>Insertive anal intercourse</td>
<td>1:1,538 (0.065%)</td>
</tr>
<tr>
<td>Receptive vaginal intercourse</td>
<td>1:1,000 (0.10%)</td>
</tr>
<tr>
<td>Insertive vaginal intercourse</td>
<td>1:2,000 (0.05%)</td>
</tr>
<tr>
<td>Receptive oral sex</td>
<td>1:10,000 (0.01%)</td>
</tr>
<tr>
<td>Insertive oral sex</td>
<td>1:20,000 (0.005%)</td>
</tr>
</tbody>
</table>

*Oral/vaginal contact is a negligible risk unless blood is present.

**Source:** Centres for Disease Control, January 2005

**Effectiveness of HIV PEP:**
HIV PEP has been shown to be effective in decreasing the risk of HIV transmission in situations such as occupational exposure and mother-to-child transmission.

- A case-control study of health-care workers who did or did not take zidovudine revealed a reduction of 81% (95% CI – 48%-94%) in the risk of HIV infection after percutaneous exposure to HIV-infected blood.
- Many mother-to-child transmission studies with many different regimens have revealed a risk reduction of at least 50% - 67% in the rate of transmission from mother to child where the mother is known to be HIV-positive.
- Studies regarding HIV PEP of non-occupational health exposure in the context of sexual assault have shown no HIV seroconversion due to HIV PEP failure.
The rationale for using HIV PEP following sexual assault is based on the above information; however, due to ethical concerns regarding study design and sample sizes and heterogeneity of exposures, research that definitively proves the effectiveness of HIV PEP following sexual assault cannot be conducted.

For that reason, many regulatory boards do not have recommendations on the use of HIV PEP in non-occupational exposure. However, there is an increasing consensus that non-occupational exposure must be taken into account when considering HIV PEP issues.²


Appendix 1B

Risk Assessment for HIV PEP (cont’d) – HIV Prevalence

In order to assist health care providers with counselling on HIV transmission and HIV PEP, the prevalence of HIV in Ontario regions and internationally are presented in the following table:

Table 3: Number and prevalence of HIV positive residents 18 years and older in Ontario by region and sex, 2008

<table>
<thead>
<tr>
<th>Region</th>
<th>MALES</th>
<th>FEMALES</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HIV Number</td>
<td>Population</td>
</tr>
<tr>
<td>Northern</td>
<td>460</td>
<td>402,425</td>
</tr>
<tr>
<td>Ottawa</td>
<td>2,650</td>
<td>407,879</td>
</tr>
<tr>
<td>Eastern</td>
<td>666</td>
<td>405,709</td>
</tr>
<tr>
<td>Toronto</td>
<td>17,045</td>
<td>1,273,971</td>
</tr>
<tr>
<td>Central East</td>
<td>1,177</td>
<td>1,691,460</td>
</tr>
<tr>
<td>Central West</td>
<td>1,480</td>
<td>1,168,692</td>
</tr>
<tr>
<td>Southwest</td>
<td>1,730</td>
<td>777,450</td>
</tr>
<tr>
<td>Total Ontario</td>
<td>25,208</td>
<td>6,127,586</td>
</tr>
</tbody>
</table>

Source: Robert Remiss, Ontario HIV Epidemiologic Monitoring Unit, Department of Public Health Sciences, University of Toronto, 2008. 2004 population estimates provided by Health Data and Decision Support Unit (HDDSU), Knowledge Management Branch, Ontario Ministry of Health and Long-Term Care.

Table 4: Countries with High HIV Prevalence (Infection Rate Greater than 5%)

Botswana
Cameroon
Central Africa Republic
Congo
Cote d’Ivoire
Gabon
Kenya
Lesotho
Malawi
Mozambique
Namibia
South Africa
Swaziland
Tanzania
Uganda
Zambia
Zimbabwe


Appendix 1c
Choice of HIV PEP

Non-pregnant adults and children ≥ 12 years old and ≥ 35 kg:
- Tenofovir/emtricitabine 300/200 mg: 1 tablet once a day x 28 days total
- Lopinavir/ritonavir 200/50 mg: 2 tablets twice a day x 28 days total

If lopinavir/ritonavir is contraindicated due to drug-drug interactions and the client is ≥ 16 years old:
- Tenofovir/emtricitabine 300/200 mg: 1 tablet once a day x 28 days total
- Raltegravir 400 mg: 1 tablet twice a day x 28 days total

Women during pregnancy:
- Zidovudine/lamivudine 300/150 mg: 1 tablet twice a day x 28 days total
- Lopinavir/ritonavir 200/50 mg: 2 tablets twice a day x 28 days total

Children < 12 years old or < 35 kg or unable to swallow pills:
- Zidovudine/Lamivudine, lopinavir/ritonavir: Dosage according to weight
See appendix 1D for adequate dosing.

Please note: Antiretrovirals are available in the following formulations:

<table>
<thead>
<tr>
<th></th>
<th>Tenofovir/Emtricitabine (Truvada®)</th>
<th>Lopinavir/ritonavir (Kaletra®)</th>
<th>Zidovudine (Retrovir®)</th>
<th>Lamivudine (3TC®)</th>
<th>Raltegravir (Isentress®)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pills</strong></td>
<td>300/200 mg tablet</td>
<td>200/50 mg tablet</td>
<td>100 mg capsules</td>
<td>150 mg tablet</td>
<td>400 mg tablet</td>
</tr>
<tr>
<td></td>
<td>100/25 mg tablet</td>
<td>300 mg tablet</td>
<td>300/150 mg tablet (Combivir®)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Oral Liquid</strong></td>
<td>None</td>
<td>80/20 mg per mL (160 mL bottle)</td>
<td>10 mg/mL (240 mL bottle)</td>
<td>10 mg/mL (240 mL bottle)</td>
<td>None</td>
</tr>
</tbody>
</table>

Trade names of antiretroviral agents:
- Tenofovir/emtricitabine: Truvada®
- Lopinavir/ritonavir: Kaletra®
- Zidovudine/lamivudine: Combivir®
- Lamivudine: 3TC®
- Raltegravir: Isentress®
### Appendix 1d

**Paediatric HIV PEP Dosage Charts**

**Table 5: Zidovudine Oral Dosage, Paediatric Patient Any Age**

<table>
<thead>
<tr>
<th>Weight (kg)</th>
<th>Dose in mg (9 mg/kg)</th>
<th>Volume per Dose in mL (10 mg/mL)</th>
<th>Dose in capsules (100 mg/caps)</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>135</td>
<td>13 mL BID</td>
<td>1 caps qam 2 caps qpm</td>
</tr>
<tr>
<td>17</td>
<td>150</td>
<td>15 mL BID</td>
<td>1 caps qam 2 caps qpm</td>
</tr>
<tr>
<td>18</td>
<td>160</td>
<td>16 mL BID</td>
<td>1 caps qam 2 caps qpm</td>
</tr>
<tr>
<td>20</td>
<td>180</td>
<td>18 mL BID</td>
<td>1 caps qam 2 caps qpm</td>
</tr>
<tr>
<td>22</td>
<td>200</td>
<td>20 mL BID</td>
<td>2 caps BID</td>
</tr>
<tr>
<td>24</td>
<td>220</td>
<td>22 mL BID</td>
<td>2 caps BID</td>
</tr>
<tr>
<td>28</td>
<td>250</td>
<td>25 mL BID</td>
<td>2 caps qam 3 caps qpm</td>
</tr>
<tr>
<td>≥ 30 kg</td>
<td>300</td>
<td>30 mL BID</td>
<td>3 caps BID</td>
</tr>
</tbody>
</table>

Pick the nearest weight to your patient for adequate dosing.

If the client has a weight ≥ 30 kg and is able to swallow pills, the client may be offered Combivir® (zidovudine/lamivudine) 1 tab BID instead of zidovudine (Retrovir®) and lamivudine (3TC®) separately.
Trade names of antiretroviral agents:  
Tenofovir/emtricitabine: Truvada®  
Lopinavir/ritonavir: Kaletra®  
Zidovudine/lamivudine: Combivir®  
Raltegravir: Isentress®  
Lamivudine: 3TC®  
Zidovudine: Retrovir®  

### Table 6: Lamivudine Oral Dosage, Paediatric Patient Any Age

<table>
<thead>
<tr>
<th>Weight (kg)</th>
<th>Dose in mg (4 mg/kg BID)</th>
<th>Volume per Dose in mL (10 mg/mL)</th>
<th>Dose in tablets (150 mg/tab)</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>60</td>
<td>6 mL BID</td>
<td>0.5 tab BID</td>
</tr>
<tr>
<td>17</td>
<td>70</td>
<td>7 mL BID</td>
<td>0.5 tab BID</td>
</tr>
<tr>
<td>20</td>
<td>80</td>
<td>8 mL BID</td>
<td>0.5 tab BID</td>
</tr>
<tr>
<td>23</td>
<td>90</td>
<td>9 mL BID</td>
<td>0.5 tab qam 1 tab qpm</td>
</tr>
<tr>
<td>25</td>
<td>100</td>
<td>10 mL BID</td>
<td>0.5 tab qam 1 tab qpm</td>
</tr>
<tr>
<td>28</td>
<td>110</td>
<td>11 mL BID</td>
<td>0.5 tab qam 1 tab qpm</td>
</tr>
<tr>
<td>30</td>
<td>120</td>
<td>12 mL BID</td>
<td>1 tab BID</td>
</tr>
<tr>
<td>33</td>
<td>130</td>
<td>13 mL BID</td>
<td>1 tab BID</td>
</tr>
<tr>
<td>≥ 35.0</td>
<td>150</td>
<td>15 mL BID</td>
<td>1 tab BID</td>
</tr>
</tbody>
</table>

Pick the nearest weight to your patient for adequate dosing.

If the client has a weight ≥ 30 kg and is able to swallow pills, the client may be offered Combivir® (zidovudine/lamivudine) 1 tab BID instead of zidovudine (Retrovir®) and lamivudine (3TC®) separately.

### Table 7: Lopinavir/ritonavir Oral Dosage, Paediatric Patient Any Age

<table>
<thead>
<tr>
<th>Weight (kg)</th>
<th>Volume per Dose in mL BID (Lopinavir 80 / Ritonavir 20 mg/mL)</th>
<th>Number of pediatric tablets (lopinavir/ritonavir 100/25 mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>15 - 25 kg</td>
<td>2.5 mL BID</td>
<td>2 tablets BID</td>
</tr>
<tr>
<td>&gt;25 – 35 kg</td>
<td>4 mL BID</td>
<td>3 tablets BID</td>
</tr>
<tr>
<td>&gt; 35 kg</td>
<td>5 mL BID</td>
<td>4 tablets BID or may give adult tablets and dose</td>
</tr>
</tbody>
</table>

December 3, 2011
Before starting your client on HIV PEP, you must be aware of the following:

### Appendix 1E

**CONTRAINDICATIONS AND PRECAUTIONS TO HIV PEP**

<table>
<thead>
<tr>
<th>Use with caution</th>
<th>Avoid use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lopinavir/ritonavir</td>
<td>♦ Acute hepatitis&lt;br&gt;♦ Advanced liver failure</td>
</tr>
<tr>
<td>♦ Stable chronic liver disease&lt;br&gt;♦ Patients with hemophilia</td>
<td></td>
</tr>
<tr>
<td>Tenofovir/emtricitabine</td>
<td>♦ Children ≤ 12 years old&lt;br&gt;♦ Pregnant women&lt;br&gt;♦ Creatinine clearance &lt; 30 ml/min</td>
</tr>
<tr>
<td>♦ Creatinine clearance of 30 – 50 ml/min&lt;br&gt;♦ Consult product monograph for dose adjustments</td>
<td></td>
</tr>
<tr>
<td>Zidovudine</td>
<td>♦ Current absolute neutrophil count &lt; 0.75 x 10^9 cells/L&lt;br&gt;♦ Current hemoglobin of &lt; 75 g/L&lt;br&gt;♦ Acute pancreatitis</td>
</tr>
<tr>
<td>♦ Current absolute neutrophil count 0.75 - 0.1 x 10^9 cells/L&lt;br&gt;♦ Current hemoglobin 75 - 90 g/L&lt;br&gt;♦ Risk factors for or history of pancreatitis (especially for children)&lt;br&gt;♦ History of bone marrow insufficiency or severe anemia&lt;br&gt;♦ Creatinine clearance of &lt; 15 ml/min&lt;br&gt;♦ Consult product monograph for dose adjustments</td>
<td></td>
</tr>
<tr>
<td>Lamivudine</td>
<td></td>
</tr>
<tr>
<td>♦ Risk factors for or history of pancreatitis (especially for children)&lt;br&gt;♦ Creatinine clearance of &lt; 50 ml/min&lt;br&gt;♦ Consult product monograph for dose adjustment</td>
<td></td>
</tr>
<tr>
<td>Zidovudine/Lamivudine</td>
<td>♦ Current absolute neutrophil count &lt; 0.75 x 10^9 cells/L&lt;br&gt;♦ Current hemoglobin of &lt; 75 g/L&lt;br&gt;♦ Acute pancreatitis&lt;br&gt;♦ Creatinine clearance of &lt; 50 ml/min&lt;br&gt;♦ Administer Retrovir and 3TC instead</td>
</tr>
<tr>
<td>♦ Current absolute neutrophil count 0.75 - 0.1 x 10^9 cells/L&lt;br&gt;♦ Current hemoglobin 75 - 90 g/L&lt;br&gt;♦ Risk factors for or history of pancreatitis (especially for children)&lt;br&gt;♦ History of bone marrow insufficiency or severe anemia</td>
<td></td>
</tr>
</tbody>
</table>

A history of hepatitis does not automatically rule out the use of HIV PEP. However, in the event of acute symptomatic illness or severely elevated liver enzymes (> 5X upper limit of normal), HIV PEP use may be contraindicated, or dosage adjustments may be necessary. The RN should consult an MD, who may want to consult an HIV expert.

**Trade names of antiretroviral agents:**

- Tenofovir/emtricitabine: **Truvada®**
- Lopinavir/ritonavir: **Kaletra®**
- Zidovudine/lamivudine: **Combivir®**
- Raltegravir: **Isentress®**
- Lamivudine: **3TC®**
- Zidovudine: **Retrovir®**
**Drug precautions and contraindications to HIV PEP:**
Non-essential medications, alternative therapies, vitamins, and recreational drug use should be discontinued during the HIV PEP regimen (e.g. medications for erectile dysfunction, herbal mood enhancers/sleep aids).

This is a table of interactions of the more commonly used drugs with the antiretrovirals that may be used in the HIV PEP regimen. This is, however, not an exhaustive list of all interactions. In case of doubt, please consult a pharmacist.

**Online resources**
- [http://www.hivclinic.ca/](http://www.hivclinic.ca/)

<table>
<thead>
<tr>
<th>Effect</th>
<th>Class</th>
<th>Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decreased Lopinavir/ritonavir efficacy</td>
<td>Anticonvulsants</td>
<td>Carbamazepine (Tegretol®); Phenobarbital; Phenytoin (Dilantin®)</td>
</tr>
<tr>
<td></td>
<td>Corticosteroids</td>
<td>Dexamethasone (Decadron®)</td>
</tr>
<tr>
<td>Anti-arrhythmics</td>
<td></td>
<td>Amiodarone (Cordarone®); Digoxin (Lanoxin®); Lidocaine (Xylocaine®); Quinidine</td>
</tr>
<tr>
<td>Antibiotics</td>
<td></td>
<td>Clarithromycin (Biaxin®); Rifabutin (Mycobutin®); Erythromycin</td>
</tr>
<tr>
<td>Anticoagulants</td>
<td></td>
<td>Warfarin (Coumadin®)</td>
</tr>
<tr>
<td>Anticonvulsants</td>
<td></td>
<td>Clonazepam (Frisium®)</td>
</tr>
<tr>
<td>Antifungals</td>
<td></td>
<td>Ketoconazole (Nizoral®); Itraconazole (Sporanox®); Voriconazole (Vfend®)</td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td></td>
<td>Clonazepam (Rivotril®)</td>
</tr>
<tr>
<td>Calcium channel blockers</td>
<td></td>
<td>Felodipine (Plendil®, Renil®, Nifedipine (Adalat®), Nicardipine (Cardene®)</td>
</tr>
<tr>
<td>Immunosuppressants</td>
<td></td>
<td>Cyclosporine (Neoral®, Sandimmune®), Tacrolimus (Prograf®)</td>
</tr>
<tr>
<td>Inhaled steroids</td>
<td></td>
<td>Fluticasone (Flonase®, Advair®, Flovent®)</td>
</tr>
<tr>
<td>Statins</td>
<td></td>
<td>Used at doses &gt; 10 mg OD: Atorvastatin (Lipitor®), Rosuvastatin (Crestor®)</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>Colchicine</td>
</tr>
<tr>
<td>Decreased drug efficacy</td>
<td>Antiparasitic</td>
<td>Atovaquone (Mepron®)</td>
</tr>
<tr>
<td></td>
<td>Narcotic analgesics</td>
<td>Methadone</td>
</tr>
<tr>
<td></td>
<td>Oral contraceptive</td>
<td>Ethinyl estradiol (contained in most birth control pills)</td>
</tr>
<tr>
<td></td>
<td>Disulfiram reaction</td>
<td>Antibiotic</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>Metronidazole</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Disulfiram</td>
</tr>
</tbody>
</table>
### Trade names of antiretroviral agents:

- **Tenofovir/emtricitabine**: Truvada®
- **Lopinavir/ritonavir**: Kaletra®
- **Zidovudine/lamivudine**: Combivir®
- **Lamivudine**: 3TC®
- **Raltegravir**: Isentress®
- **Zidovudine**: Retrovir®

### Table

<table>
<thead>
<tr>
<th>Effect</th>
<th>Class</th>
<th>Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decreased Lopinavir/ritonavir efficacy</td>
<td>Antibiotics</td>
<td>Rifampin (Rifadin&lt;sup&gt;®&lt;/sup&gt;)</td>
</tr>
<tr>
<td></td>
<td>Herbal products</td>
<td>St. John’s Wort (Hypericum perforatum)</td>
</tr>
<tr>
<td>Prolonged sedation and/or respiratory depression</td>
<td>Benzodiazepines</td>
<td>Midazolam (Versed&lt;sup&gt;®&lt;/sup&gt;); Triazolam (Halcion&lt;sup&gt;®&lt;/sup&gt;)</td>
</tr>
<tr>
<td></td>
<td>Neuroleptics</td>
<td>Pimozide (Grop&lt;sup&gt;®&lt;/sup&gt;)</td>
</tr>
<tr>
<td>Life-threatening arrhythmias</td>
<td>Anti-arrhythmics</td>
<td>Flecaïnide (Tambocor&lt;sup&gt;®&lt;/sup&gt;); Propafenone (Rythmol&lt;sup&gt;®&lt;/sup&gt;)</td>
</tr>
<tr>
<td></td>
<td>Antihistamines</td>
<td>Astemizole (Hismanol&lt;sup&gt;®&lt;/sup&gt;); Terfenadine (Seldane&lt;sup&gt;®&lt;/sup&gt;)</td>
</tr>
<tr>
<td></td>
<td>GI motility agents</td>
<td>Cisapride (Propulsid&lt;sup&gt;®&lt;/sup&gt;)</td>
</tr>
<tr>
<td>Potential life-threatening drug toxicity</td>
<td>Ergot derivatives</td>
<td>All drugs in this class. E.g., Dihydroergotamine (Migranal&lt;sup&gt;®&lt;/sup&gt;); Ergotamine (Bellergal&lt;sup&gt;®&lt;/sup&gt;; Cafergot&lt;sup&gt;®&lt;/sup&gt;; Ergomar&lt;sup&gt;®&lt;/sup&gt;; Ergodyr&lt;sup&gt;®&lt;/sup&gt;; Graverol&lt;sup&gt;®&lt;/sup&gt;); Ergonovine; Methylergometrine (Methergin&lt;sup&gt;®&lt;/sup&gt;); Ergot mesylates (Hydergin&lt;sup&gt;®&lt;/sup&gt;)</td>
</tr>
<tr>
<td></td>
<td>Statins</td>
<td>Lovastatin (Mevacor&lt;sup&gt;®&lt;/sup&gt;); Simvastatin (Zocor&lt;sup&gt;®&lt;/sup&gt;)</td>
</tr>
</tbody>
</table>

### Lopinavir/ritonavir

- **Contraindicated**
- To be used with caution

### Raltegravir

- To be used with caution

### Tenofovir/emtricitabine

- **To be used with caution**

### Zidovudine

- **To be used with caution**

### Potent inducers of UGT1A1

- Rifampin (Rifadin<sup>®</sup>)

### Decreased Raltegravir efficacy

- Decreased drug efficacy

### Antiretroviral

- Atazanavir (Reyataz<sup>®</sup>)

### Additive renal toxicity

- **Anti-inflammatory**

- All systemic anti-inflammatory agents. E.g., Aspirin, Celecoxib (Celebrex<sup>®</sup>); Diclofenac; Ibuprofen (Advil<sup>®</sup>; Motrin<sup>®</sup>; Robaxin platinum<sup>®</sup>); Naproxen

- **Antifungal**

- Amphotericin B (Ambisome<sup>®</sup>)

- **Antibacterial**

- Gentamicin, tobramycin, vancomycin

- **Antiviral**

- Adefovir, Cidofovir, Ganciclovir (Cytovene<sup>®</sup>); Valacyclovir (Valtrex<sup>®</sup>); Valganciclovir (Valcyte<sup>®</sup>)

### Decreased Zidovudine efficacy

- Decreased Zidovudine efficacy

- Antiretrovirals

- Stavudine (Zert<sup>®</sup>)

### Increased zidovudine toxicity

- Anticonvulsant

- Phenytoin (Dilantin<sup>®</sup>); Valproic acid (Depakene<sup>®</sup>; Epival<sup>®</sup>)

- **Antifungal**

- Fluconazole (Diflucan<sup>®</sup>)

- **Antiprotozoal**

- Atovaquone (Mepron<sup>®</sup>)

- **Narcotic analgesics**

- Methadone

- **Uncoumarins**

- Probenecid (Benuryl<sup>®</sup>)
Due to drug interactions, the following drugs are either to be used with caution or contraindicated when the client is taking the corresponding antiretroviral. Each drug is listed by drug class followed by an exhaustive list of all drugs within that class that may interact with the antiretroviral unless otherwise specified. Not all drugs within each drug class are targeted – only the drugs listed may interact with the antiretroviral.

If the client is on any of these medications and ≥16 years old, replace Kaletra with Isentress 400 mg tablets, one tablet twice daily. If the client is < 16 years old, consult with the designated MD who may want to contact a paediatric HIV expert. If the RN has any concerns about interactions with any other drug, contact an MD or Pharmacist before, or at the client’s follow-up visit.

As Kaletra® may decrease the effectiveness of long-term use hormonal contraceptives including , patch, and vaginal ring; a barrier form of contraceptive (e.g., condom) should be used.

---

### Trade names of antiretroviral agents:

- Tenofovir/emtricitabine: Truvada®
- Lopinavir/ritonavir: Kaletra®
- Zidovudine/lamivudine: Combivir®
- Lamivudine: 3TC®
- Zidovudine: Retrovir®

---

<table>
<thead>
<tr>
<th>Effect</th>
<th>Class*</th>
<th>Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additive bone marrow suppression</td>
<td>Antivirals</td>
<td>Ganciclovir (Cytovene®), Cidofovir</td>
</tr>
<tr>
<td></td>
<td>Antibiotics</td>
<td>Trimethoprim-sulfamethoxazole (Septra®), Dapsone</td>
</tr>
<tr>
<td></td>
<td>Antifungals</td>
<td>Amphotericin B (Ambisome®)</td>
</tr>
<tr>
<td></td>
<td>Biological response modifiers</td>
<td>Interferon alpha (Roferon-A®, Intron-A®, Rebetron®)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effect</th>
<th>Class*</th>
<th>Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additive pancreatic toxicity</td>
<td>Antimetabolite</td>
<td>Hydroxyurea (Hydrea®)</td>
</tr>
<tr>
<td></td>
<td>Antibiotic</td>
<td>Pentamidine IV</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effect</th>
<th>Class*</th>
<th>Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decreased Zidovudine/Lamivudine efficacy</td>
<td>Antiretrovirals</td>
<td>Stavudine (Zerit®)</td>
</tr>
<tr>
<td></td>
<td>Anticonvulsant</td>
<td>Phenytoin (Dilantin®), Valproic acid (Depakene®, Epival®)</td>
</tr>
<tr>
<td></td>
<td>Antifungal</td>
<td>Fluconazole (Diflucan®)</td>
</tr>
<tr>
<td></td>
<td>Antiprotozoal</td>
<td>Atovaquone (Mepron®)</td>
</tr>
<tr>
<td></td>
<td>Narcotic analgesics</td>
<td>Methadone</td>
</tr>
<tr>
<td></td>
<td>Uricosuric</td>
<td>Probenecid (Benuryl®)</td>
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</table>

<table>
<thead>
<tr>
<th>Effect</th>
<th>Class*</th>
<th>Drugs</th>
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<tbody>
<tr>
<td>Additive bone marrow suppression</td>
<td>Antivirals</td>
<td>Ganciclovir (Cytovene®), Cidofovir</td>
</tr>
<tr>
<td></td>
<td>Antibiotics</td>
<td>Trimethoprim-sulfamethoxazole (Septra®), Dapsone</td>
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<tr>
<td></td>
<td>Antifungals</td>
<td>Amphotericin B (Ambisome®)</td>
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<tr>
<td></td>
<td>Biological response modifiers</td>
<td>Interferon alpha (Roferon-A®, Intron-A®, Rebetron®)</td>
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<tr>
<td></td>
<td>Additive pancreatic toxicity</td>
<td>Antimetabolite</td>
</tr>
<tr>
<td></td>
<td>Antibiotic</td>
<td>Pentamidine IV</td>
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</tbody>
</table>
Appendix 1F

Referral to Physician and/or HIV Expert

| MD Referral: | The RN must consult with the designated MD when one or more of the following conditions exist. |
| HIV Expert Referral: | The MD should consider consulting an HIV expert when one or more of the following conditions exist. If the RN has a direct relationship with the HIV expert, the RN can refer directly to her/him. |

Consultation with HIV expert strongly recommended
- The client has been assaulted by an assailant known to be HIV-positive and will require consideration for additional or alternative prophylactic anti-HIV medication ($\leq 72$ hrs).
  - RN and MD should immediately provide HIV PEP when the victim/survivor is initially seen
  - Local HIV expert must be consulted as soon as possible during working hours to make arrangements for a consultative visit (i.e. same or next day).*
- The client was assaulted by a known HIV-positive assailant and penetration occurred but the time since the assault was greater than 72 hours.**
- The client has any contraindications to HIV PEP including renal impairment, acute or advanced liver failure or acute pancreatitis, bone marrow suppression or severe anaemia, or is taking a contraindicated medication.
- Consultation with a paediatric HIV expert is strongly recommended for all clients < 12 years or < 35 kg

Consultation with HIV expert recommended
- The client presents with an existing severe medical problem (e.g. kidney disease, cancer)
- The client is pregnant. There is an unknown degree of risk of teratogenesis in the first trimester from the HIV PEP medications.***
- The client’s baseline HIV test returns positive.
- The client is currently taking HIV PEP and is having adherence difficulty.

Consultation with HIV expert should be considered
- The client’s bloodwork at baseline or week 2 are abnormal. The HIV PEP therapy may need to be discontinued or changed.
- The client develops severe HIV PEP-related side effects including rash or new symptoms while taking the HIV PEP medication. The HIV PEP therapy may need to be discontinued or changed.
- The RN’s discretion for any additional concerns.

* In such a case, the HIV expert may consider continuing the anti-HIV therapy for longer than the 28 days due to the high risk of seroconversion.
** Anti-HIV therapy may be started in this scenario not as HIV PEP but as early treatment for acute HIV infection.
*** Antiretroviral drugs are potentially teratogenic in the first trimester of pregnancy and are therefore often avoided during this period. However, if a woman is at high risk of seroconversion after a sexual assault, the risk of transmission to the fetus is very high due to the high viral load during the acute seroconversion phase of the disease. Therefore, giving antiretroviral drugs in this scenario is more important than the theoretical risk of teratogenesis.
Appendix 1g

Obtaining HIV Blood Storage Sample

To provide a guide to health care providers obtaining a client’s blood sample to be frozen for seven months for potential future HIV testing. The following steps are recommended:

1. Discuss with client the risk of contracting HIV from a sexual assault. The risk of contracting HIV from a sexual assault is unknown, but is estimated to be very low in most cases. Risk of HIV infection with sexual assault is thought to increase with certain factors associated with the assault (e.g., type of exposure, assailant risk level/HIV status, type(s) of injury).

2. Explain the purpose of the HIV blood sample for hold to the client. A client blood sample can be obtained and frozen for up to seven months, allowing time for the client to obtain HIV antibody testing at 4-6 weeks and three- and six-months post-sexual assault. Reassure the client that the HIV blood sample is held in a secure and private location and that it will only be used as a baseline reference if she or he tests positive for the HIV virus at the 4-6 week, three- or six-month test and then wishes to know her/his HIV status at the time of the assault.

3. Discuss HIV seroconversion time with the client. Conversion to a positive test usually takes about three months from the time of exposure, although the virus has been detected as early as four weeks. It is rare for seroconversion to occur past 6 months.

4. Obtain and document consent for the storage of client blood sample at the initial visit for a potential future HIV test.

5. Obtain client HIV blood sample for hold and send to appropriate secure and private storage facility to be frozen.

6. Explain to client the importance of HIV testing at 4-6 weeks, three- and six months post-assault.

7. Inform client that they must contact SA/DVTC staff within seven months of their initial visit for the HIV blood for hold to be tested, and if they do not contact SA/DVTC staff within this timeframe, the blood sample will be destroyed.

8. Document the date HIV blood sample for hold will be destroyed in the client’s chart: seven months after initial SA/DVTC visit.

9. Review condom use and other safe sex practices with client. Encourage use of condoms until client HIV test at week 4-6, three- and six-months are known by client to be negative.

Note: Storage of blood for later HIV testing is for at-risk clients who declined HIV PEP. For those clients who accepted HIV PEP, client HIV testing is recommended at the initial visit or at day 2-4 during client follow-up to ensure that the client is not already HIV-positive (which would alter treatment).
ONTARIO SA/DVTC MEDICAL GUIDELINES FOR ADMINISTRATION OF FOLLOW-UP DOSES OF HIV POST-EXPOSURE PROPHYLAXIS

Prepared April 2003
Last revised December 2011

SUBJECT:
Medical Guidelines for Registered Nurses (RNs) and Medical Doctors (MDs) for Administration of Follow-Up Doses for HIV Post-Exposure Prophylaxis

PURPOSE:
To provide guidance to (RNs) working with (MDs) on administering the follow-up doses of HIV post-exposure prophylaxis (HIV PEP) to sexual assault victims/survivors who started the 5-day starter kit and want to continue the 28-day regimen.

Under these guidelines and medical directives, the follow-up RNs will carry out the sexual assault-related management, counselling, laboratory testing, HIV testing and the provision of HIV PEP medications. In SA/DVTCs not using medical directives, an MD will write the prescription for the HIV PEP which will be available through the SA/DVTC’s pharmacy. The MD consulted should be willing to participate in the follow-up process.

USE:
To be administered to any sexual assault victim/survivor who starts the 5-day HIV PEP starter kit and who provides consent to complete the HIV PEP regimen.

During the first visit to the SA/DVTC, the RN administered a 5-day HIV PEP starter kit to the client. Five follow-up visits are scheduled during the 28-day course of HIV PEP. Three of these visits require the provision of additional HIV PEP medications to complete the course of treatment. HIV PEP drug regimens and dosage are described in Appendix 1C.

CONTRAINDICATIONS AND DRUG INTERACTIONS:
Complete details regarding contraindications, drug interactions and precautions to HIV PEP are outlined in Appendix 1E*.

Side Effects:
The follow-up RN must obtain a history of client side effects. If the client is experiencing severe side effects (i.e. diarrhoea, nausea, headache, weakness, muscle aching, rash), the RN is to consult an MD and the MD may want to consult an HIV expert.

Severe, potentially life-threatening, and fatal skin reactions including Stevens Johnson syndrome, toxic epidermal necrolysis (TEN) have been reported with raltegravir. Hypersensitivity reactions have also been reported and were characterized by rash, constitutional findings, and sometimes, organ dysfunction, including hepatic failure. Discontinue raltegravir and other suspect agents immediately if signs or symptoms of severe skin reactions or hypersensitivity reactions develop (including, but not limited to, severe rash or rash accompanied by fever, general malaise, fatigue, muscle or joint aches, blisters, oral lesions, conjunctivitis, facial edema, hepatitis, eosinophilia,
Abnormal Bloodwork results:
The follow-up RN should review the bloodwork done at baseline and week 2. The HIV PEP medications should be reconsidered in clients who are experiencing drug interactions or abnormal results listed in Appendix E.

If the above laboratory abnormalities occur, the follow-up RN should consult an MD, who then may want to consult an HIV expert.

Follow-up blood counts must be done at week 2 to assess HIV PEP drug toxicity. These include Complete Blood Count, blood glucose, creatinine, AST, ALT, ALP, total billirubin, WBC and differential, amylase, and β-HCG. Clients with a history of chronic kidney or liver disease require additional baseline hepatic function tests (i.e., albumin, INR, PT, and PTT). The following tests are recommended if not completed at the initial visit: Hepatitis C Ab, Hepatitis B Ab and Ag, and VDRL. The HIV PEP medications may need to be stopped or the dose adjusted. In the case of abnormal laboratory results, the follow-up RN should consult the MD, who may want to consult an HIV expert.

Non-essential medications and alternative therapies including vitamins should be discontinued during HIV PEP. Recreational drug use should also be discontinued for the length of the HIV PEP regimen.

Birth Control and Pregnancy:
Lopinavir/ritonavir can decrease the effectiveness of long-term use hormonal contraceptives in pill, patch, and vaginal ring formulations therefore a barrier form of contraceptive (e.g., condom) should be used.

The use of Tenofovir/emtricitabine and Lopinavir/ritonavir during pregnancy has not been extensively studied. Nonetheless, this is the most frequently used antiretroviral regimen in pregnant women living with HIV and is the regimen of choice based on efficacy studies completed in adults and clinical experience during pregnancy. Antiretroviral drugs are often avoided in the first trimester due to general concerns of teratogenesis. However if the assailant is known to be HIV-positive or has HIV risk factors, the risk of HIV transmission outweighs the risk of teratogenesis, and HIV PEP should be continued regardless of the client’s pregnancy status. If the client is pregnant, the RN is advised to consult the SA/DVTC’s designated MD and the MD should consult an HIV expert.

NON-PREGNANT ADULTS AND CHILDREN ≥12 YEARS OLD AND ≥ 35 KG:
The following should be given to complete the 28-day course.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dosage</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tenofovir/emtricitabine 300/200 mg</td>
<td>1 tablet once a day x 23 days over 3 visits</td>
<td></td>
</tr>
<tr>
<td>Lopinavir/ritonavir 200/50 mg</td>
<td>2 tablets twice a day x 23 days over 3 visits</td>
<td></td>
</tr>
<tr>
<td>Raltegravir 400 mg</td>
<td>1 tablet twice a day x 23 days over 3 visits</td>
<td></td>
</tr>
</tbody>
</table>

If lopinavir/ritonavir is contra-indicated due to drug interaction and the client is ≥ 16 years old, replace lopinavir/ritonavir with:

- Raltegravir 400 mg 1 tablet twice a day x 23 days over 3 visits
PREGNANCY:
The following should be given to complete the 28-day course.
- Zidovudine/lamivudine 300/150 mg: 1 tablet twice a day x 23 days over 3 visits
- Lamivudine: 3TC®
- Zidovudine: Retrovir®

CHILDREN <12 YEARS OLD OR <35 KG OR UNABLE TO SWALLOW TABLETS:
- Zidovudine/lamivudine: 300/150 mg: 1 tablet twice a day x 23 days

* If the RN has any concerns regarding drug interactions, contact an MD or pharmacist before or at the client's follow-up visit.

MEDICAL GUIDELINE PRACTICE COMPONENTS:
At each follow-up visit, the RN will review with the client:
- The risk of HIV transmission
- Side effects experienced
- How the client can best take HIV PEP medication (twice a day with food)
- The importance of not missing a dose

The RN will endeavour to answer any HIV PEP related questions posed by the client.

SECOND VISIT (DAY 2-4 FOLLOWING INITIAL VISIT TO SA/DVTC):
If the client has decided to continue taking HIV PEP, provide her/him with a further supply of HIV PEP therapy:

NON-PREGNANT ADULTS AND CHILDREN ≥12 YEARS OLD AND ≥35 KG:
- Tenofovir/emtricitabine 300/200 mg: 1 tablet once a day x 10 days (10 tablets)
- Lopinavir/ritonavir 200/50 mg: 2 tablets twice a day x 10 days (40 tablets)
  - If lopinavir/ritonavir is contra-indicated due to drug interaction and the client is ≥ 16 years old, replace lopinavir/ritonavir with:
    - Raltegravir 400 mg: 1 tablet twice a day x 10 days (20 tablets)

PREGNANCY:
- Zidovudine/lamivudine 300/150 MG: 1 tablet twice a day x 10 days (20 tablets)
- Lopinavir/ritonavir 200/50 mg: 2 tablets twice a day x 10 days (40 tablets)

CHILDREN <12 YEARS OLD OR <35 KG OR UNABLE TO SWALLOW TABLETS:
- Zidovudine/lamivudine, lopinavir/ritonavir: x 1 bottle each

An HIV test should be performed at this visit if one was not done at the initial visit. If the client blood sample was taken and stored at the initial visit, the client should be asked if this sample can be tested for HIV. Pre-test counselling must be done at this time. Client consent should be obtained by the RN prior to obtaining a client blood sample for HIV testing. This process should be documented in the client chart.

Trade names of antiretroviral agents:
- Tenofovir/emtricitabine: Truvada®
- Lopinavir/ritonavir: Kaletra®
- Zidovudine/lamivudine: Combivir®
- Lamivudine: 3TC®
- Raltegravir: Isentress®
- Zidovudine: Retrovir®
Ontario Public Health Laboratories will expedite HIV test results if “STAT” is written on the requisition.

The RN should evaluate the client’s initial visit blood test results and if abnormal, the designated MD should be consulted. Laboratory tests may need to be repeated.

HIV PEP medications should be reconsidered and the designated MD consulted if any abnormal lab results are present, see Appendix E:

**THIRD VISIT (WEEK 1 FOLLOW-UP):**
The RN should review the side effects of HIV PEP medications with the client, how she/he can best take HIV PEP medications (twice a day with or without food) and review the importance of not missing a dose. This visit can be done in-person or by phone.

The designated MD should be consulted if the client is experiencing severe HIV PEP-related side effects such as diarrhoea, nausea, headache, weakness, muscle aching or rash.

**FOURTH VISIT (WEEK 2 FOLLOW-UP):**
If the client has decided to continue to take HIV PEP, the RN will provide the client with a further 7 days of HIV PEP therapy:

**NON-PREGNANT ADULTS AND CHILDREN ≥12 YEARS OLD AND ≥ 35 KG:**

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dosage</th>
<th>Dosing Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tenofovir/emtricitabine</td>
<td>300/200 mg</td>
<td>1 tablet once a day x 7 days (7 tablets)</td>
</tr>
<tr>
<td>Lopinavir/ritonavir</td>
<td>200/50 mg</td>
<td>2 tablets twice a day x 7 days (28 tablets)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If lopinavir/ritonavir is contra-indicated due to drug interaction and the client is ≥ 16 years old, replace lopinavir/ritonavir with:</td>
</tr>
<tr>
<td>Raltegravir</td>
<td>400 mg</td>
<td>1 tablet twice a day x 7 days (14 tablets)</td>
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</table>

**PREGNANCY:**

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dosage</th>
<th>Dosing Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zidovudine/lamivudine</td>
<td>300/150 mg</td>
<td>1 tablet twice a day x 7 days (14 tablets)</td>
</tr>
<tr>
<td>Lopinavir/ritonavir</td>
<td>200/50 mg</td>
<td>2 tablets twice a day x 7 days (28 tablets)</td>
</tr>
</tbody>
</table>

**CHILDREN <12 YEARS OLD OR < 35 KG OR UNABLE TO SWALLOW TABLETS:**

| Medication                  | | |
|-----------------------------| | |
| Zidovudine/lamivudine, lopinavir/ritonavir | Ensure sufficient supply for the next 7 days |

Client blood tests to assess HIV PEP drug toxicity should be done at the week 2 client visit and should include a Complete Blood Count blood glucose, creatinine, AST, ALT, ALP, total bilirubin, WBC and differential, amylase, and β-HCG. Clients with a history of chronic kidney or liver disease require additional baseline hepatic function tests (i.e., albumin, INR, PT, and PTT). The following tests are recommended if not completed at the initial visit: Hepatitis C Ab, Hepatitis B Ab and Ag, and VDRL.

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**Trade names of antiretroviral agents:**

- Tenofovir/emtricitabine: Truvada®
- Lopinavir/ritonavir: Kaletra®
- Zidovudine/lamivudine: Combivir®
- Raltegravir: Isentress®
- Lamivudine: 3TC®
- Zidovudine: Retrovir®

December 3, 2011
**Fifth Visit (Week 3 Follow-up):**
If the client has decided to continue to take HIV PEP, the RN will provide the client a further supply of HIV PEP therapy based on local dispensing protocol:

**NON-PREGNANT ADULTS AND CHILDREN ≥12 YEARS OLD AND ≥ 35KG:**
- Tenofovir/emtricitabine 300/200 mg: 1 tablet once a day x 6 days (6 tablets)
- Lopinavir/ritonavir 200/50 mg: 2 tablets twice a day x 6 days (24 tablets)
  - If lopinavir/ritonavir is contra-indicated due to drug interaction and the client is ≥ 16 years old, replace lopinavir/ritonavir with:
    - Raltegravir 400 mg: 1 tablet twice a day x 6 days (12 tablets)

**PREGNANCY:**
- Zidovudine/lamivudine 300/150 mg: 1 tablet twice a day x 6 days (12 tablets)
- Lopinavir/ritonavir 200/50 mg: 2 tablets twice a day x 6 days (24 tablets)

**CHILDREN <12 YEARS OLD OR < 35 KG OR UNABLE TO SWALLOW TABLETS:**
- Zidovudine/lamivudine, lopinavir/ritonavir: Ensure sufficient supply for the next 6 days

The RN will evaluate the week 2 client laboratory test results and if abnormal, the designated MD should be consulted.

HIV PEP medications should be reconsidered and the designated MD consulted if any abnormal laboratory results are present, see Appendix E.

**NOTE: FIFTH VISIT & FINAL VISIT:**
The RN must inform the client that she or he should have follow-up HIV testing at week 4-6 and at months 3 and 6 after the initial visit. The client can have this HIV testing done at the SA/DVTC, his or her family MD or at an anonymous HIV test centre.

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**Trade names of antiretroviral agents:**
- Tenofovir/emtricitabine: Truvada®
- Lopinavir/ritonavir: Kaletra®
- Zidovudine/lamivudine: Combivir®
- Lamivudine: 3TC®
- Raltegravir: Isentress®
- Zidovudine: Retrovir®

**December 3, 2011**
## Appendix 2A

### Flow Chart of SA/DVTC Visits

<table>
<thead>
<tr>
<th></th>
<th>First visit</th>
<th>Second Visit (Day 2 – 5)</th>
<th>Third Visit (Week 1)</th>
<th>Fourth Visit (Week 2)</th>
<th>Fifth Visit (Week 3)</th>
<th>Final Visit (Week 4)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ALL VICTIMS/SURVIVORS</strong></td>
<td></td>
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</tr>
<tr>
<td>Counsel on HIV risk</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Give “HIV Risk” Client Handout</td>
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<tr>
<td><strong>VICTIMS/SURVIVORS AT RISK NOT TAKING HIV PEP</strong></td>
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<tr>
<td>Counsel on HIV PEP</td>
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</tr>
<tr>
<td>Recommend HIV testing¹</td>
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</tr>
<tr>
<td><strong>VICTIMS/SURVIVORS WHO TAKE HIV PEP</strong></td>
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<tr>
<td>Counsel on HIV PEP</td>
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<tr>
<td>Give HIV PEP Information Booklet</td>
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<td>Pregnancy test²</td>
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<td>Bloodwork³</td>
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<td>Recommend HIV testing⁴</td>
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<tr>
<td>Review presence of side effects</td>
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<td>√</td>
<td>√</td>
<td>√</td>
<td>√</td>
</tr>
</tbody>
</table>

¹ HIV testing is recommended to be stored at the first visit and follow-up testing should be done at week 4-6, and month 3 and 6 after the assault

² STAT serum β-HCG must be done at first visit, repeat in follow-up if there is a concern

³ Bloodwork includes Complete Blood Count, blood glucose, creatinine, AST, ALT, ALP, total bilirubin, WBC and differential, amylase. Clients with a history of chronic kidney or liver disease require additional baseline hepatic function tests (i.e., albumin, INR, PT, and PTT). The following tests are recommended if not completed at the initial visit: Hepatitis C Ab, Hepatitis B Ab and Ag, and VDRL

⁴ HIV testing is recommended to be stored at the first visit

⁵ Week 1 can be done as a phone call or an in-person visit

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**Trade names of antiretroviral agents:**

- Tenofovir/emtricitabine: Truvada®
- Lopinavir/ritonavir: Kaletra®
- Zidovudine/lamivudine: Combivir®
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