ONTARIO SEXUAL ASSAULT/
DOMESTIC VIOLENCE TREATMENT CENTRES (SA/DVTCs)

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

Appendices:
1A Risk Assessment for HIV Post-Exposure Prophylaxis
1B Risk Assessment (cont’d) – HIV Prevalence
1C Choice of HIV PEP
1D Paediatric HIV PEP Dosage Charts
1E Contraindications and Precautions to HIV PEP
1F Referral to Physician and/or HIV Expert
1G Obtaining an HIV Blood Sample for Storage

2. MEDICAL GUIDELINES– HIV PEP FOLLOW-UP

ONTARIO SA/DVTC MEDICAL GUIDELINES FOR ADMINISTRATION OF FOLLOW-UP
DOSES OF HIV POST-EXPOSURE PROPHYLAXIS

Appendix:
2A Flow Chart of Visits

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April 2003
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Latest revision November 2015

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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 include tenofovir/emtricitabine (Truvada®), Dolutegravir (Tivicay®), raltegravir (Isentress®), zidovudine/lamivudine (Combivir®).

Two different regimens are suggested for different populations:
- Adults and children ≥ 12 years old and pregnant women: tenofovir/emtricitabine (Truvada) and dolutegravir (Tivicay)
- Children < 12 years old or unable to swallow tablets: lamivudine/zidovudine (Combivir) and raltegravir (Isentress)

The Ministry of Health and Long-Term Care endorses this program and has provided funding for HIV PEP medications for all at-risk sexual assault victims/survivors receiving care at any of Ontario’s 35 SA/DVTCs.
- Heterosexual HIV transmission has increased since 2005, though likely due to changes made in the exposure category hierarchy (29.6% of new infections in Canada, 2013)
- 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), Nurse Practitioners (NPs) 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. Or a physician/NP will write an order for the five day HIV PEP starter kit which will be provided by the SADVTC program RN.

Each SA/DVTC will be linked with an HIV expert. Each SA/DVTC can contact or consult their assigned HIV expert for any HIV-related issues.

Trade names of antiretroviral agents:
- Tenofovir/emtricitabine: Truvada®
- Zidovudine/lamivudine: Combivir®
- Lamivudine: 3TC®
- Raltegravir: Isentress®
- Zidovudine: Retrovir®
USE:
HIV PEP is used to decrease the risk of transmission of HIV after sexual assault. In adults, children ≥ 12 years old and pregnant women, it consists of a 28-day course of tenofovir/emtricitabine and dolutegravir.

In children less than 12 years old, or unable to swallow tablets, zidovudine, lamivudine and raltegravir 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). Considering the speed at which HIV replicates in the human body, HIV PEP must be started as soon as possible after exposure, ideally within 2 hours. Decisions regarding initiation of HIV PEP beyond 72 hours after the exposure should be made on a case-by-case basis with the realization that diminished efficacy is a consequence of delay in the timing of initiation.

**DOSAGE (≥12 YEARS OLD - PREGNANT OR NON-PREGNANT):**
- Tenofovir 300 mg/emtricitabine 200 mg 1 tablet once a day x 5 days
- Dolutegravir 50 mg 1 tablet once a day x 5 days

**PEDIATRIC MEDICATIONS (<12 YEARS OLD OR UNABLE TO SWALLOW TABLETS):**
- Zidovudine, lamivudine, raltegravir
  - Dose according to weight

The drugs 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 should have baseline bloodwork done – CBC (if taking Combivir), blood glucose (if taking Combivir), creatinine, AST, ALT, ALP, bilirubin, and HcG (female).

Clients with a history of chronic kidney or liver disease require additional baseline hepatic function tests (i.e., albumin, INR PT, and PTT). 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 a MD/NP, who then may want to consult an HIV specialist.

**Tenofovir/emtricitabine** requires dose adjustment in renal impairment: administer 1 tablet every 48 hours if creatinine clearance is between 30-49 mL/min. Tenofovir/emtricitabine should be avoided in clients who have a creatinine clearance ≤ 30 mL/min or are receiving hemodialysis.

**Dolutegravir** is not indicated and should be avoided in clients who are < 12 years of age.

**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 1 for a list of all contraindicated medications

The use of tenofovir/emtricitabine is not recommended in children < 12 years old. 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.

Non-essential medications (e.g. medications for erectile dysfunction) and complementary/alternate therapy 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.

Clients who are on oral contraceptive medications should continue them. None of the regimens suggested decrease the efficacy of oral contraceptives.

Dolutegravir may be administered without regard to meals, but should be administered 2 hours prior or 6 hours after cation-containing antacids or laxatives, sucralfate, oral supplements containing iron, calcium or magnesium. If taken with food, dolutegravir may be taken at the same time as calcium or iron supplements.

Raltegravir may be co-administered with calcium carbonate (supplement or antacid), but should not be administered at all with antacids containing aluminum or magnesium.

**Trade names of antiretroviral agents:**
- Tenofovir/emtricitabine: Truvada®
- Zidovudine/lamivudine: Combivir ®
- Lamivudine: 3TC ®
- Raltegravir: Isentress ®
- Zidovudine: Retrovir ®
In 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 there are any additional concerns for the client who is pregnant, the RN is advised to consult an MD/NP, who may wish to consult an HIV expert.

If the client is <12 years old, the RN is advised to consult an HIV paediatrician after the 1st dose of lamivudine, zidovudine and raltegravir have been given.
MEDICAL GUIDELINE PRACTICE COMPONENTS:

IMMEDIATE CARE FOR ALL CLIENTS

1. Acute medical urgency needs of clients must always take precedence over the discussion of HIV PEP.

2. Determine time elapsed since the assault. Decision regarding the initiation of HIV PEP beyond 72 hours should be made on a case-by-case basis with the realization that diminished efficacy is a consequence of the delay in the timing of initiation. Ideally, it should be started within 2 hours of the exposure.

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 a MD/NP 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, a paediatric HIV expert should be contacted immediately.

   If the client is at any risk of HIV acquisition, the RN and MD/NP 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).

Trade names of antiretroviral agents:
Tenofovir/emtricitabine: Truvada
Zidovudine/lamivudine: Combivir ®
Lamivudine: STC ®
Raltegravir: Isentress ®
Zidovudine: Retrovir ®
A single dose of tenofovir/emtricitabine with dolutegravir or zidovudine/lamivudine with 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 age < 12 years) 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/NP 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 MD/NPs at end of this section*.

14. If the client is < 12 years old, inform the MD/NP 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.

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**Trade names of antiretroviral agents:**

- Tenofovir/emtricitabine: Truvada
- 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.

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* consult a MD/NP. The MD/NP should determine the doses of zidovudine, lamivudine and raltegravir using the *Paediatric HIV PEP Dosage Charts (see Appendix 1D)*. The MD/NP 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 (pregnant or non-pregnant)*, 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); dolutegravir 1 tablet orally once a day for 5 days (5 tablets total; 4 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 blood for CBC (if taking Combivir), blood glucose (if taking Combivir), creatinine, AST, ALT, ALP, bilirubin, and a STAT serum beta-HCG (for women).

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 the days 2 – 4 if storage of blood is not possible at your SA/DVTC. This option requires an additional blood draw.

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**Trade names of antiretroviral agents:**

- Tenofovir/emtricitabine: Truvada
- 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.

25. Arrange for follow-up in 2-4 days and explain the follow-up procedures to the client. 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, and 4 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, she should use barrier precautions (e.g., condom) to avoid pregnancy and to prevent possible transmission of sexually transmitted infections to sexual partners.
   ♦ Breastfeeding can be continued.
   ♦ Dolutegravir may be administered without regard to meals, but should be administered 2 hours prior OR 6 hours after cation-containing antacids or laxatives, sucralfate, oral supplements containing iron, calcium or magnesium. If taken with food, dolutegravir may be taken at the same time as calcium or iron supplements.
   ♦ Raltegravir may be coadministered with calcium carbonate (supplement or antacid), but should not be administered at all with antacids containing aluminum or magnesium.

**Note to RNs and MD/NPs - 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 sero-conversion after a sexual assault, the risk of transmission to the fetus is very high due to the high viral load during the acute sero-conversion 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 dolutegravir are contraindicated, alternate regimens will be covered with the MOHLTC funding.

**Trade names of antiretroviral agents:**

Tenofovir/emtricitabine: Truvada
Zidovudine/lamivudine: Combivir ®
Lamivudine: 3TC ®
Raltegravir: Isentress ®
Zidovudine: Retrovir ®
Appendix 1A

Risk Assessment for HIV Post-Exposure Prophylaxis (HIV PEP)

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 1:

<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>Needlesharing in IV drug use</td>
<td>1:149 (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 (Penetration by a penis)</td>
<td>1:200 (0.5%)</td>
</tr>
<tr>
<td>Insertive anal intercourse (Penetrating with the penis)</td>
<td>1:1,538 (0.065%)</td>
</tr>
<tr>
<td>Receptive vaginal intercourse (Penetration by a penis)</td>
<td>1:1,000 (0.10%)</td>
</tr>
<tr>
<td>Insertive vaginal intercourse (Penetrating with the penis)</td>
<td>1:2,000 (0.05%)</td>
</tr>
<tr>
<td>Receptive oral sex (Penetration by a penis)</td>
<td>1:10,000 (0.01%)*</td>
</tr>
<tr>
<td>Insertive oral sex (Penetrating with the penis)</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

Trade names of antiretroviral agents:
Tenofovir/emtricitabine: Truvada
Zidovudine/lamivudine: Combivir ®
Lamivudine: 3TC ®
Raltegravir: Isentress ®
Zidovudine: Retrovir ®
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\(^1\).
- 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.\(^2\)\(^-\)\(^5\)
- 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.\(^6\)\(^-\)\(^9\)
- 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.\(^2\)


\(^3\) European Project on Non-Occupational Post Exposure Prophylaxis. 2002. Management of non-occupational post exposure prophylaxis to HIV: Sexual, injection drug user or other exposures.


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>HIV Number</th>
<th>Population</th>
<th>HIV Prevalence</th>
<th>HIV Number</th>
<th>Population</th>
<th>HIV Prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Northern</td>
<td>460</td>
<td>402,425</td>
<td>0.114%</td>
<td>166</td>
<td>407,834</td>
<td>0.041%</td>
</tr>
<tr>
<td>Ottawa</td>
<td>2,650</td>
<td>407,879</td>
<td>0.650%</td>
<td>713</td>
<td>421,709</td>
<td>0.169%</td>
</tr>
<tr>
<td>Eastern</td>
<td>666</td>
<td>405,709</td>
<td>0.164%</td>
<td>118</td>
<td>413,155</td>
<td>0.029%</td>
</tr>
<tr>
<td>Toronto</td>
<td>17,045</td>
<td>1,273,971</td>
<td>1.338%</td>
<td>2,413</td>
<td>1,339,508</td>
<td>0.180%</td>
</tr>
<tr>
<td>Central East</td>
<td>1,177</td>
<td>1,691,460</td>
<td>0.070%</td>
<td>373</td>
<td>1,712,104</td>
<td>0.022%</td>
</tr>
<tr>
<td>Central West</td>
<td>1,480</td>
<td>1,168,692</td>
<td>0.127%</td>
<td>449</td>
<td>1,192,830</td>
<td>0.038%</td>
</tr>
<tr>
<td>Southwest</td>
<td>1,730</td>
<td>777,450</td>
<td>0.223%</td>
<td>347</td>
<td>792,621</td>
<td>0.044%</td>
</tr>
<tr>
<td>Total Ontario</td>
<td>25,208</td>
<td>6,127,586</td>
<td>0.411%</td>
<td>4,579</td>
<td>6,279,761</td>
<td>0.073%</td>
</tr>
</tbody>
</table>

Source: Robert Remis, 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%)

<table>
<thead>
<tr>
<th>MALES</th>
<th>FEMALES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botswana</td>
<td>Mozambique</td>
</tr>
<tr>
<td>Cameroon</td>
<td>Namibia</td>
</tr>
<tr>
<td>Central Africa Republic</td>
<td>South Africa</td>
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<tr>
<td>Congo</td>
<td>Swaziland</td>
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<td>Cote d'Ivoire</td>
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<td>Gabon</td>
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<td>Kenya</td>
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<td>Lesotho</td>
<td>Zimbabwe</td>
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<tr>
<td>Malawi</td>
<td></td>
</tr>
</tbody>
</table>


Trade names of antiretroviral agents:
Tenofovir/emtricitabine: Truvada
Zidovudine/lamivudine: Combivir ®
Lamivudine: 3TC ®
Raltegravir: Isentress ®
Zidovudine: Retrovir ®
Appendix 1c

Choice of HIV PEP

Adults women, and children ≥ 12 years old (pregnant or non-pregnant):
- Tenofovir/emtricitabine: 1 tablet once a day x 28 days total
- Dolutegravir: 1 tablet once a day x 28 days total

Children < 12 years old or unable to swallow pills:
- Zidovudine, lamivudine, raltegravir: Dosage according to weight

Please note: Antiretrovirals are available in the following formulations:

<table>
<thead>
<tr>
<th>Pills</th>
<th>Tenofovir/Emtricitabine (Truvada®)</th>
<th>Dolutegravir (Tivicay®)</th>
<th>Zidovudine (Retrovir®)</th>
<th>Lamivudine (3TC®)</th>
<th>Raltegravir (Isentress®)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>300/200 mg tablet</td>
<td>50 mg tablet</td>
<td>100 mg capsules</td>
<td>150 mg tablet</td>
<td>400 mg tablet</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>300 mg tablet</td>
<td>300 mg tablet</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>300/150 mg tablet (Combivir®)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral Liquid</td>
<td>none</td>
<td>none</td>
<td>10 mg/mL (240 mL bottle)</td>
<td>10 mg/mL (240 mL bottle)</td>
<td>100 mg chewable pediatric tablet</td>
</tr>
</tbody>
</table>

Trade names of antiretroviral agents:
- Tenofovir/emtricitabine: Truvada
- 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</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2 caps qpm</td>
</tr>
<tr>
<td>17</td>
<td>150</td>
<td>15 mL BID</td>
<td>1 caps qam</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2 caps qpm</td>
</tr>
<tr>
<td>18</td>
<td>160</td>
<td>16 mL BID</td>
<td>1 caps qam</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2 caps qpm</td>
</tr>
<tr>
<td>20</td>
<td>180</td>
<td>18 mL BID</td>
<td>1 caps qam</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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.
### 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: Raltegravir Oral Dosage, Paediatric Patient Any Age

<table>
<thead>
<tr>
<th>Weight (kg)</th>
<th>Dose in mg</th>
<th>Dose in chewable tablets (100 mg/tab)</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>100 mg BID</td>
<td>1 tab BID</td>
</tr>
<tr>
<td>17</td>
<td>100 mg BID</td>
<td>1 tab BID</td>
</tr>
<tr>
<td>20</td>
<td>150 mg BID</td>
<td>1 ½ tab BID</td>
</tr>
<tr>
<td>23</td>
<td>150 mg BID</td>
<td>1 ½ tab BID</td>
</tr>
<tr>
<td>25</td>
<td>150 mg BID</td>
<td>1 ½ tab BID</td>
</tr>
<tr>
<td>28</td>
<td>200 mg BID</td>
<td>2 tabs BID</td>
</tr>
<tr>
<td>30</td>
<td>200 mg BID</td>
<td>2 tabs BID</td>
</tr>
<tr>
<td>33</td>
<td>200 mg BID</td>
<td>2 tabs BID</td>
</tr>
<tr>
<td>35</td>
<td>200 mg BID</td>
<td>2 tabs BID</td>
</tr>
<tr>
<td>38</td>
<td>200 mg BID</td>
<td>2 tabs BID</td>
</tr>
<tr>
<td>40</td>
<td>300 mg BID</td>
<td>3 tabs BID</td>
</tr>
</tbody>
</table>

Pick the nearest weight to your patient for adequate dosing.
## Appendix 1e

### CONTRAINDICATIONS AND PRECAUTIONS TO HIV PEP

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

### HEALTH PRECAUTIONS AND CONTRAINDICATIONS TO HIV PEP:

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic</th>
<th>Use with caution</th>
<th>Avoid use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Truvada</td>
<td>Tenofovir/emtricitabine</td>
<td>❖ Creatinine clearance of 30-50 ml/min * Consult product monograph for dose adjustments</td>
<td>❖ Children &lt; 12 years old&lt;br&gt;❖ Creatinine clearance &lt; 30 ml/min</td>
</tr>
<tr>
<td>Zidovudine</td>
<td></td>
<td>❖ Current absolute neutrophil count 0.75-0.1 x 10⁹ 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 * Consult product monograph for dose adjustments</td>
<td>❖ Current absolute neutrophil count &lt; 0.75 x 10⁹ cells/L&lt;br&gt;❖ Current hemoglobin of &lt; 75 g/L&lt;br&gt;❖ Acute pancreatitis</td>
</tr>
<tr>
<td>Lamivudine</td>
<td></td>
<td>❖ Risk factors for or history of pancreatitis (especially for children)&lt;br&gt;❖ Creatinine clearance of &lt; 50 ml/min * Consult product monograph for dose adjustment</td>
<td></td>
</tr>
<tr>
<td>Combivir</td>
<td>Zidovudine/Lamivudine</td>
<td>❖ Current absolute neutrophil count 0.75-0.1 x 10⁹ 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>❖ Current absolute neutrophil count &lt; 0.75 x 10⁹ 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>Tivicay</td>
<td>Dolutegravir</td>
<td>❖ Underlying Hepatitis B/c co-infection. Monitor liver chemistries carefully.</td>
<td>❖ Children &lt; 12 years old&lt;br&gt;❖ Adolescents &lt; 40 Kg&lt;br&gt;❖ Not in combination with dofetilide</td>
</tr>
<tr>
<td>Isentress</td>
<td>Raltegravir</td>
<td>With those on strong inducers of uridine diphosphate glucuronosyltransferase (UGT) 1A1 (ex rifampin)</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 a MD/NP and the MD/NP may want to consult an HIV expert.

**DRUG PRECAUTIONS AND CONTRAINDICATIONS TO HIV PEP:**

Non-essential medications, alternate therapy and vitamins, and recreational drug use should be discontinued during the HIV PEP regimen (e.g. medications for erectile dysfunction, herbal mood enhancers/sleep aids).

Dolutegravir may be administered without regard to meals, but should be administered 2 hours prior or 6 hours after cation-containing antacids or laxatives, sucralfate, oral supplements containing iron, calcium or magnesium. If taken with food, dolutegravir may be taken at the same time as calcium or iron supplements.

Raltegravir may be co-administered with calcium carbonate (supplement or antacid), but should not be administered at all with antacids containing aluminum or magnesium.

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>Drug</th>
<th>Effect</th>
<th>Class</th>
<th>Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tenofovir/Emtricitabine</strong></td>
<td>To be used with caution</td>
<td>Decreased drug efficacy</td>
<td>Antiretroviral Atazanavir (Reyataz*)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Additive renal toxicity</td>
<td>Anti-inflammatory All systemic anti-inflammatory agents. Eg., Aspirin, Celecoxib (Celebrex); Diclofenac; Ibuprofen (Advil*, Motrin*, Robax platinum*) Naproxen</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Antifungal Amphotericin B, (Ambisome*)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Antibacterial Gentamicin, tobramycin, vancomycin</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Antiviral Adefovir; Cidofovir; Ganciclovir (Cytovene*); Valacyclovir (Valtrex*); Valganciclovir (Valcyte*)</td>
</tr>
<tr>
<td></td>
<td>Contraindicated</td>
<td>Potentially serious adverse event</td>
<td>Antiretroviral Didanosine (Videx*)</td>
</tr>
<tr>
<td><strong>Zidovudine</strong></td>
<td>To be used with caution</td>
<td>Decreased Zidovudine efficacy</td>
<td>Antiretrovirals Stavudine (Zerit*)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Increased zidovudine toxicity</td>
<td>Anticonvulsant Phenytoin (Dilantin*); Valproic acid (Depakene*, Epival*)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Antifungal Fluconazole (Diflucan*)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Antiprotozoal Atovaquone (Mepron*)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Narcotic Analgesics Methadone</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Uricosuric Probencid (Benuryl*)</td>
</tr>
<tr>
<td><strong>Lamivudine</strong></td>
<td>T be used with</td>
<td>Additive pancreatic toxicity</td>
<td>Antimetabolite Hydroxyureca</td>
</tr>
</tbody>
</table>

**Trade names of antiretroviral agents:**
- Tenofovir/emtricitabine: Truvada ®
- Zidovudine/lamivudine: Combierv ®
- Lamivudine: 3TC®
- Zidovudine: Retrovir ®
- Raltegravir: Isentress ®
<table>
<thead>
<tr>
<th>Caution</th>
<th>Antibiotic</th>
<th>Pentamidine IV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Zidovudine/Lamivudine</strong></td>
<td><strong>Decreased efficacy</strong></td>
<td></td>
</tr>
<tr>
<td>To be used with caution</td>
<td><strong>Antiretrovirals</strong></td>
<td>Stavudine</td>
</tr>
<tr>
<td></td>
<td><strong>Anticonvulsant</strong></td>
<td>Phenytoin, Valproic Acid</td>
</tr>
<tr>
<td></td>
<td><strong>Antifungal</strong></td>
<td>Fluconazole</td>
</tr>
<tr>
<td></td>
<td><strong>Antiprotozoal</strong></td>
<td>Atovaquone</td>
</tr>
<tr>
<td></td>
<td><strong>Narcotic Analgesics</strong></td>
<td>Methadone</td>
</tr>
<tr>
<td></td>
<td><strong>Uricosuric</strong></td>
<td>Probenacid</td>
</tr>
<tr>
<td></td>
<td><strong>Additive Bone Marrow Suppression</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Antivirals</strong></td>
<td>Ganciclovir, Cidofovir</td>
</tr>
<tr>
<td></td>
<td><strong>Antibiotics</strong></td>
<td>Septra, Dapson</td>
</tr>
<tr>
<td></td>
<td><strong>Antifungals</strong></td>
<td>Amphotericin B</td>
</tr>
<tr>
<td></td>
<td><strong>Biologics</strong></td>
<td>Interferon Alpha</td>
</tr>
<tr>
<td></td>
<td><strong>Antimetabolite</strong></td>
<td>Hydroxyurea</td>
</tr>
<tr>
<td></td>
<td><strong>Antibiotic</strong></td>
<td>Pentamidine IV</td>
</tr>
<tr>
<td></td>
<td><strong>Additive Pancreatic Toxicity</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Tivicay/Dolutegravir</strong></td>
<td><strong>Decreased concentration of tivicay</strong></td>
<td></td>
</tr>
<tr>
<td>To be used with caution</td>
<td><strong>Anticonvulsant</strong></td>
<td>Oxcarbazepine, phenytoin, phenobarbital, Carbemazapine</td>
</tr>
<tr>
<td></td>
<td><strong>Diabetes</strong></td>
<td>Metformin</td>
</tr>
<tr>
<td></td>
<td><strong>Supplements</strong></td>
<td>St. John’s Wort, Calcium, Iron supplements</td>
</tr>
<tr>
<td><strong>Isentress/Raltegravir</strong></td>
<td><strong>Decreased concentration</strong></td>
<td></td>
</tr>
<tr>
<td>To be used with caution</td>
<td><strong>Steroid</strong></td>
<td>Dexamethasone</td>
</tr>
<tr>
<td></td>
<td><strong>Anticonvulsant</strong></td>
<td>Phenobarbital, phenytoin</td>
</tr>
<tr>
<td></td>
<td><strong>Antiretroviral</strong></td>
<td>Ritonavir</td>
</tr>
<tr>
<td></td>
<td><strong>Antibiotic</strong></td>
<td>Rifampin</td>
</tr>
<tr>
<td></td>
<td><strong>Supplement</strong></td>
<td>St. John’s Wort</td>
</tr>
<tr>
<td></td>
<td><strong>Increased concentration</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Antiretroviral</strong></td>
<td>Atazanavir</td>
</tr>
<tr>
<td></td>
<td><strong>NSAID</strong></td>
<td>Diclofenac</td>
</tr>
<tr>
<td></td>
<td><strong>Antifungal</strong></td>
<td>Ketoconazol</td>
</tr>
<tr>
<td></td>
<td><strong>Uricosuric</strong></td>
<td>Probenacid</td>
</tr>
<tr>
<td></td>
<td><strong>Immunosuppressant</strong></td>
<td>Tacrolimus</td>
</tr>
</tbody>
</table>

* 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.
<table>
<thead>
<tr>
<th>Effect</th>
<th>Class</th>
<th>Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Zidovudine</strong></td>
<td>To be used with caution</td>
<td>Additive bone marrow suppression</td>
</tr>
<tr>
<td></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>
<tr>
<td></td>
<td>Lamivudine</td>
<td>To be used with caution</td>
</tr>
<tr>
<td></td>
<td>Additive pancreatic toxicity</td>
<td>Antimetabolite</td>
</tr>
<tr>
<td></td>
<td>Antibiotic</td>
<td>Pentamidine IV</td>
</tr>
<tr>
<td><strong>Zidovudine/Lamivudine</strong></td>
<td>To be used with caution</td>
<td>Decreased Zidovudine/Lamivudine efficacy</td>
</tr>
<tr>
<td></td>
<td>Antiretrovirals</td>
<td>Stavudine (Zerit*)</td>
</tr>
<tr>
<td></td>
<td>Increased Zidovudine/Lamivudine toxicity</td>
<td>Anticonvulsant</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>Uromeric</td>
<td>Probenecid (Benuryl*)</td>
</tr>
<tr>
<td></td>
<td>To be used with caution</td>
<td>Additive bone marrow suppression</td>
</tr>
<tr>
<td></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>
<tr>
<td></td>
<td>Additive pancreatic toxicity</td>
<td>Antimetabolite</td>
</tr>
<tr>
<td></td>
<td>Antibiotic</td>
<td>Pentamidine IV</td>
</tr>
</tbody>
</table>

**Dolutegravir**

**Raltegravir**

**Trade names of antiretroviral agents:**
- Tenofovir/emtricitabine: Truvada ®
- Zidovudine/lamivudine: Combivir ®
- Lamivudine: STC®
- Zidovudine: Retrovir ®
- Raltegravir: Isentress ®
### Appendix 1F

**Referral to Physician, Nurse Practitioner and/or HIV Expert**

<table>
<thead>
<tr>
<th>MD/NP Referral:</th>
<th>The RN must consult with the designated MD/NP when one or more of the following conditions exist.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV Expert Referral:</td>
<td>The MD/NP 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.</td>
</tr>
</tbody>
</table>

**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 (≤ 72 hrs).
  - RN and MD/NP 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 arrange 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

**Consultation with HIV expert recommended**

- The client presents with an existing severe medical problem (e.g. kidney disease, cancer)

- 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 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 sero-conversion.
** Anti-HIV therapy may be started in this scenario not as HIV PEP but as early treatment for acute HIV infection.
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 four 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, and four-month test and then wishes to know her/his HIV status at the time of the assault.

3. Discuss HIV sero-conversion 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 sero-conversion to occur past 4 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, and four 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 condom until client HIV test at week 4-6 weeks and four-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).

Trade names of antiretroviral agents:
Tenofovir/emtricitabine: Truvada ®
Lamivudine: 3TC®
Zidovudine/lamivudine: Combivir ®
Zidovudine: Retrovir ®
Raltegravir: Isentress ®
ONTARIO SA/DVTC MEDICAL GUIDELINES FOR ADMINISTRATION OF FOLLOW-UP DOSES OF HIV POST-EXPOSURE PROPHYLAXIS

Prepared April 2003
Last revised November 2015

Note: The HIV PEP follow-up schedule may vary at SADVTC’s depending on staffing, travel distance for patients.

SUBJECT:
Medical Guidelines for Registered Nurses (RNs) Working with Medical Doctors (MDs)/Nurse Practitioners (NPs) for Administration of Follow-Up Doses for HIV Post-Exposure Prophylaxis

PURPOSE:
To provide guidance to Registered Nurses (RNs) working with Medical Doctors (MDs)/Nurse Practitioners (NPs) 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, the counselling, the laboratory testing, the HIV testing and the follow-up. In SA/DVTCs not using medical directives MD/NP will write the prescription for the HIV PEP which will be available through the SA/DVTC’s pharmacy. The MD/NP 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. Four follow-up visits must occur during the 28-day course of HIV PEP. These visits will require the administration of additional HIV PEP to complete the course. 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), the RN is to consult an MD/NP and the MD/NP may want to consult an HIV expert.

Abnormal Bloodwork results:
The follow-up RN should review the bloodwork done at baseline and week 2. The HIV PEP drugs should be stopped in clients who have:
◆ A hemoglobin < 90 g/L
◆ An absolute neutrophil count < 500 cells/μL
◆ A Platelet count < 20,000 cells/μL
◆ AST, ALT, ALP or bilirubin > 5 X ULN
◆ A serum creatinine rise > 15 μmol/L

Trade names of antiretroviral agents:
Tenofovir/emtricitabine: Truvada ®
Zidovudine/lamivudine: Combivir ®
Lamivudine: 3TC®
Zidovudine: Retrovir ®
Raltegravir: Isentress ®
If the above laboratory abnormalities occur, the follow-up RN should consult a MD/NP/NP, who then may want to consult an HIV expert.

It should be noted that dolutegravir can cause an increase in serum creatinine of 10-15 μmol/L due to inhibition of renal OCT2, which does NOT reflect an actual change in renal function. This rise is expected within the first few weeks of starting and should remain stable. It returns to baseline shortly after stopping the drug.

Follow-up blood counts (CBC), renal (electrolytes, creatinine and urea) and hepatic function tests (AST, ALT, ALP, bilirubin), blood glucose and amylase must be done at week 2 to assess HIV PEP drug toxicity. The HIV PEP medications may need to stopped or the dose adjusted. In the case of abnormal laboratory results, the follow-up RN should consult the MD/NP and the MD/NP, who may want to consult an HIV expert.

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

**Pregnancy:**

The use of Tenofovir/emtricitabine and dolutegravir during pregnancy has not been extensively studied. Nonetheless, this is 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/NP and the MD/NP should consult an HIV expert.

**ADULTS, PREGNANT WOMEN, AND CHILDREN ≥12 YEARS OLD**

The following should be given to complete the 28-day course.

- Tenofovir/emtricitabine: 1 tablet once a day x 23 days over 4 visits
- Dolutegravir: 1 tablet once a day X 23 days over 4 visits

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

The following should be given to complete the 28-day course

- Zidovudine, lamivudine, raltegravir x 23 days over 4 visits

* If the RN has any concerns regarding drug interactions, contact a MD/NP 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 (once or 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 5 days of HIV PEP therapy:

ADULTS, PREGNANT WOMEN, AND CHILDREN ≥12 YEARS OLD
- Tenofovir/emtricitabine 1 tablet once a day x 5 days (5 tablets)
- Dolutegravir 1 tablet once a day x 5 days (5 tablets)

CHILDREN <12 YEARS OLD OR UNABLE TO SWALLOW TABLETS:
- Zidovudine, lamivudine, raltegravir 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.

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/NP should be consulted.

HIV PEP drugs should be stopped and the designated MD/NP consulted if any of these lab results are present:
- A hemoglobin < 90 g/L
- An absolute neutrophil count < 500 cells/µL
- A Platelet count < 20,000 cells/µL
- AST, ALT, ALP or bilirubin > 5 X ULN
- A serum creatinine rise > 15 µmol/L

THIRD VISIT (WEEK 2 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 (once or twice a day with or without food) and review the importance of not missing a dose. If the client has decided to continue to take HIV PEP, the RN will provide the client with a further 5 days of HIV PEP medication.

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

Trade names of antiretroviral agents:

- Tenofovir/emtricitabine: Truvada ®
- Zidovudine/lamivudine: Combivir ®
- Lamivudine: 3TC®
- Raltegravir: Isentress ®
- Zidovudine: Retrovir ®
FOURTH VISIT (WEEK 3 FOLLOW-UP):
If the client has decided to continue to take HIV PEP, the RN will provide the client with a further 5 days of HIV PEP therapy:

**ADULTS, PREGNANT WOMEN AND CHILDREN ≥12 YEARS OLD:**
- Tenofovir/emtricitabine: 1 tablet once a day x 5 days (5 tablets)
- Dolutegravir: 1 tablet once a day x 5 days (5 tablets)

**CHILDREN <12 YEARS OLD OR UNABLE TO SWALLOW TABLETS:**
- Zidovudine, lamivudine, raltegravir: Ensure sufficient supply for the next 5 days

Client blood tests to assess HIV PEP drug toxicity should be done at the week 2 client visit and should include a CBC, electrolytes, blood glucose, creatinine, urea, AST, ALT, ALP, bilirubin, and amylase.

FIFTH VISIT (WEEK 4 FOLLOW-UP):
If the client has decided to continue to take HIV PEP, the RN will provide the client a further 8 days of HIV PEP therapy:

**ADULTS, PREGNANT WOMEN AND CHILDREN ≥12 YEARS OLD:**
- Tenofovir/emtricitabine: 1 tablet once a day x 8 days (8 tablets)
- Dolutegravir: 1 tablet once a day x 8 days (8 tablets)

**CHILDREN <12 YEARS OLD OR UNABLE TO SWALLOW TABLETS:**
- Zidovudine, lamivudine, raltegravir: Ensure sufficient supply for the next 8 days

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

HIV PEP drugs should be stopped and the designated MD/NP consulted if any of these laboratory results are present:
- A hemoglobin < 90 g/L
- An absolute neutrophil count < 500 cells/μL
- A Platelet count < 20,000 cells/μL
- AST, ALT, ALP or bilirubin > 5 X ULN
- A serum creatinine rise > 15 μmol/L

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 4 months after the initial visit. The client can have this HIV testing done at the SA/DVTC, his or her family MD/NP or at an anonymous HIV test centre.
## 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 2&lt;sup&gt;1&lt;/sup&gt;)</th>
<th>Fourth Visit (Week 3)</th>
<th>Fifth Visit (Week 4)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ALL VICTIMS/SURVIVORS</strong></td>
<td></td>
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<td></td>
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<tr>
<td>Counsel on HIV risk</td>
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<td></td>
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<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>
<td>Recommend HIV testing&lt;sup&gt;1&lt;/sup&gt;</td>
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<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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<tr>
<td>Pregnancy test&lt;sup&gt;2&lt;/sup&gt;</td>
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<td>Bloodwork&lt;sup&gt;3&lt;/sup&gt;</td>
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<tr>
<td>Recommend HIV testing&lt;sup&gt;4&lt;/sup&gt;</td>
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<tr>
<td>Give HIV PEP medications</td>
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<td>√</td>
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<tr>
<td>Review presence of side effects</td>
<td></td>
<td>√</td>
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</tr>
</tbody>
</table>

<sup>1</sup>HIV testing is recommended to be stored at the first visit and follow-up testing should be done at week 4-6, And four months after the assault  
<sup>2</sup> STAT serum Beta-HCG must be done at first visit  
<sup>3</sup> Bloodwork includes CBC, electrolytes, Cr, AST, ALT, ALP, bilirubin, blood glucose and  
<sup>4</sup> HIV testing is recommended to be stored at the first visit and follow-up testing should be done at

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**Trade names of antiretroviral agents:**  
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