



Lakeridge
Health

MEDICAL DIRECTIVE

HIV Post Exposure Prophylaxis for Sexual Assault Victims

Approved by/Date: Medical Advisory Committee – June 26, 2012

Authorizing physician(s)

Physician of the Domestic Violence/Sexual Assault Care Centre (DV/SACC)
Emergency Department Physicians – LH Oshawa Only

Authorized to who

Registered Nurses working at the DV/SACC who have been certified as a Sexual Assault Nurse Examiner (SANE) or nurses that hold the knowledge, skill and judgment that work within the DV/SACC Program.

Patient Description / Population

To be initiated within 72 hours post assault with any victim who has been sexually assaulted when vaginal, anal or oral penetration with a penis has occurred, regardless of condom use or ejaculation, or with any victim who does not remember the sexual assault.

Medical Directive Description/Physician's Order

Combivir (Zidovudine 300 mg/Lamivudine 150 mg) 1 tablet po BID for 7 days

Kaletra (Lopinavir/Ritonavir 200/50) 2 tablets po BID for 7 days

Both drugs may be taken together at the same time and should be taken with food.

Specific conditions/circumstances that must be met before the Directive can be implemented

- Acute medical urgency needs must always take precedence over the discussion of HIV Post Exposure Prophylaxis (PEP).
- Carry out the HIV transmission risk assessment using the “Risk Assessment for HIV Prophylaxis” found on [Appendix A](#).
- The SANE must take a health history including history related to medication (including alternative therapies and vitamins), recreational drug use, kidney, liver, pancreatic and blood diseases to identify contraindications.
- If antiretroviral medication is necessary, obtain a current medication list from the client including prescription, non-prescription, and illicit drugs and cross-reference utilizing electronic medication information database (e.g. Lexicomp) to ensure there are no drug interactions. This should be completed prior to initiation of any post exposure prophylaxis (PEP) medications. If there are any questions or concerns, the Prescriber can discuss with a LH Pharmacist during pharmacy department business hours. After hours, a Pharmacist is available for consultation through Telehealth (Pharmacist

Originating Committee: Emergency Program Council, March 26, 2012

Medical Advisory Committee: June 26, 2012

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available 7 days a week - 7:00 – 23:00). Obtain and provide client with a 7 day supply of medications, client medication information and instruction sheets.

- Thoroughly discuss the PEP Checklist on [Appendix B](#).
- Have the client sign the consent specific to starting HIV PEP.
- If the assailant is known HIV-positive, the client MUST be offered Combivir and Kaletra immediately due to the critical aspect of timing. Delayed starting of HIV PEP reduces the effectiveness in this very high-risk situation. An HIV expert will be contacted as soon as possible during working hours for a consultation.
- If the client is classified as high or unknown risk of HIV acquisition, the SANE should consider giving the first dose of Combivir and Kaletra immediately (with food if possible) due to the critical aspect of timing. The rationale for giving HIV PEP dose immediately before counseling is that if the client was infected, the virus has already started replicating and every minute counts for the HIV PEP to work. The entire routine sexual assault procedure can take hours which is too long to wait to start the PEP. Delayed starting of the HIV PEP reduces its effectiveness at preventing HIV infection. The SANE can discuss the risk of HIV and PEP at this time or can wait until after completing the Sexual Assault Evidence Kit depending on the situation (e.g. anxiety of client about HIV, urgency of completing Kit).
- If the client is deemed no risk using the risk assessment, reassure of zero risk of transmission of HIV; indicate that PEP is not recommended and no follow-up for HIV is required.
- If the client is greater than or equal to 12 years of age and greater than or equal to 50 kg and has agreed to take PEP, give him or her the rest of the 7-day adult dose of the STARTER KIT.
- If the client is greater than or equal to 12 years of age and is less than 50 kg in weight and has agreed to take HIV PEP, SANE must consult with the designated MD to obtain a telephone order for appropriate dose of medications. The designated MD may consult the LHC pharmacist.
- If the client is less than 12 years of age and has agreed to take PEP, the SANE must consult the designated MD to obtain a telephone order for the appropriate dose of medications. The designated MD may consult an HIV expert and/or the LHC Pharmacist.
- Educate the client and ensure the client understands how to take the drugs and is aware of the possible side effects and understands the process to follow if side effects are experienced.
- All clients who decide to take PEP should have baseline bloodwork done (CBC, electrolytes, blood sugar, creatinine, urea, AST, ALT, ALP, bilirubin CK, amylase, albumin, PT AND PTT). A history of hepatitis does not automatically rule out the use of PEP. However, in the event of acute symptomatic illness or severely elevated liver enzymes (greater than five



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times upper limit of normal), PEP use may be contraindicated, or dosage adjustments may be necessary. The nurse will consult an MD and the MD may want to consult an HIV/Infectious Diseases expert.

- If after hours Fax all pertinent information on client to the Positive Care Clinic and instruct the client to call them as soon as possible to book a follow-up appointment.
- All other routine procedures carried out for sexual assault including the evidence collection that the client chooses should be provided and completed.
- Obtain urine BHCG and check results.

Contraindications to the implementation of the Directive

The patient is pregnant.

Combivir is contraindicated in clients who have:

- Taken myelosuppressive or hemotoxic drugs within 2 weeks of starting PEP drugs
- A history of bone marrow insufficiency or severe anemia; and/or
- Acute pancreatitis

Kaletra is contraindicated in clients who have:

- Acute or advanced liver failure
- Kaletra interacts with many different drugs by affecting the liver cytochrome P450 drug metabolizing enzymes. If the client is on any interacting medications, SANE must consult with the designated MD. Physician may contact Pharmacist for additional assistance with drug interactions.
- Hypersensitivity (eg, Stevens-Johnson syndrome, erythema multiforme) to lopinavir, ritonavir, or any component of the formulation; coadministration with medications highly dependent upon CYP3A4 for clearance for which increased levels are associated with serious and/or life-threatening events; coadministration with strong CYP3A4 inducers, including cisapride, ergot alkaloids (eg, dihydroergotamine, ergonovine, ergotamine, methylegonovine), lovastatin, midazolam (oral), pimozide, rifampin, simvastatin, St John's wort, triazolam
- Kaletra can decrease the effectiveness of long term use of birth control pills, so a barrier form of contraceptive (e.g. condom) should be used.

Consult electronic database (e.g. Lexicomp available on the WAVE) for review of potential drug interactions.

Non-essential medications, alternate therapy and vitamins, and recreational drug use should be discontinued during the HIV PEP regimen.



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If it is suspected that the client is emotionally unstable and/or risk for overdosing, it is recommended to use Combivir alone or not to use HIV PEP at all. Consult DV/SACC MD or HIV expert.

The use of Combivir and Kaletra during pregnancy has not been extensively studied. Antiretroviral drugs are often avoided in the first trimester due to general concerns of teratogenesis. 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 PEP should be given immediately regardless of the client's pregnancy status. If the client is pregnant, the SANE is advised to consult an MD, who may wish to consult an HIV expert.

The safety of Combivir and Kaletra in breastfeeding has not been established. Clients who begin HIV PEP should discontinue breastfeeding. Clients who choose not to take the HIV PEP should be informed that the rate of HIV transmission in breast milk is approximately 1 in 4 in order for them to make informed choices about breastfeeding.

Identify relevant Delegated Control Act or Added Skill associated with this Directive

Dispensing a drug as defined in clause 117(1) of the *Drug and Pharmacies Regulation Act*.

Documentation requirements

- On the medication order form document client's name, the date and time of the administration, as well as the dose given and site of administration.
- Signature of the SANE and date must also be recorded
- Document on client treatment and follow-up form, client should be seen in the Positive Care Clinic within 7 days
- Record all consultations in the Nursing Notes

Review/Evaluation Process

Review to be done on a biannual basis. Review to be conducted by the DV/SACC Medical Director and the DV/SACC RN

Related Documents

None

References

- Ontario Network of Sexual Assault and Domestic Violence Treatment Centres-Medical Guidelines for HIV Post Exposure Prophylaxis for Sexual Assault Survivors (2011)
- Ontario Network of Sexual Assault and Domestic Violence Treatment Centres-Medical Directives (2011)



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- College of Nurses of Ontario (2012)
- Canadian Guidelines on Sexually Transmitted Infections, Public Health Agency of Canada (2006)
- Positive Care Clinic-Lakeridge Health (2012)



**Appendix A
Risk Assessment for HIV Prophylaxis**

There are two factors that contribute to the risk of HIV transmission following sexual assault:

- 1) The risk that the assailant is HIV positive
- 2) The risk of the exposure

High Risk: Strongly Recommend HIV PEP

<p>HIGH-RISK EXPOSURE Anal penetration* Vaginal penetration* Oral penetration *, # Unknown exposure (e.g. drug assisted)</p>	PLUS	<p>HIGH-RISK ASSAILANT Known HIV positive assailant Known high-risk assailant: injection drug user; man with sexual contact with men; from endemic area</p>	<p>GUIDELINES Strongly recommend HIV PEP Combivir (AZT/3TC) & Kaletra Provide counseling and education</p>
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Unknown Risk: Discuss HIV PEP

<p>HIGH RISK EXPOSURE Anal penetration* Vaginal penetration* Oral penetration *, # Unknown exposure (e.g. drug assisted)</p>	PLUS	<p>UNKNOWN-RISK ASSAILANT Unknown or Known with unknown HIV status</p>	<p>GUIDELINES Discuss HIV PEP Combivir (AZT/3TC) & Kaletra Provide counseling and education</p>
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No Risk: Do not offer or recommend HIV PEP

<p>NO RISK EXPOSURE No vaginal penetration No anal penetration No oral penetration</p>	PLUS	<p>ANY ASSAILANT</p>	<p>GUIDELINES Do NOT offer or recommend HIV PEP - Provide counseling and education about the zero risk of acquisition and the high risk of unnecessary side effects</p>
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NOTE: If the exposure is no risk and the assailant is HIV positive, HIV PEP is not offered.

* Penetration= attempted, partial or completed penetration or ejaculation in mouth, on vagina or anus.

Oral penetration – victim/survivor forced to perform fellatio on assailant



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Appendix B

PEP Checklist:

Read This Through With the Client

give them a copy; have them sign a copy for the chart

- The patient has no medical history that would contraindicate PEP, such as liver or kidney diseases, bone marrow dyscrasia, acute pancreatitis, severe anemia
- The patient is not knowingly allergic to any of the PEP medications
- The patient is not currently taking any of the contraindicated medications found on an electronic drug interaction database (eg Lexicomp). If there are concerns, check with pharmacy, DV/SACC MD or HIV expert (through Locating).
- Do not give to a pregnant patient, contact DV/SACC MD or HIV expert
- Suggest to patient to remain on birth control during PEP regime. **Note:** Kaletra can decrease the effectiveness of oral birth control pills. Additional birth control should be used. Condoms should be worn for additional birth control and to provide barrier protection for HIV until client has been cleared of HIV infection.
- Do not become pregnant
- Suggest to female patient not to breastfeed during PEP regime
- Ensure patient understands the risks of HIV infection and the risks of taking PEP
- Ensure patient understands how to take the medication
- Discuss support systems they may have in place or how to access
- Suggest patient call the Positive Care Clinic or go to the Family Physician or the Emergency department if they are experiencing any side effects
- Suggest patient drink more fluids (water) while on PEP
- Remind patient that only by adherence to regime will PEP work effectively
- Stress the importance of attending follow up visits to the Positive Care Clinic while on PEP
- Do not donate blood, plasma, tissue, organs or sperm
- Do not share toothbrushes, razors, needles etc. that could be contaminated with blood or body fluids
- Non-essential medications and alternate therapy including vitamins should be discontinued during HIV PEP. Recreational drug use should also be discontinued

Signature of Patient or Substitute Decision Maker

Date