

# HIV PEP FOLLOWING SEXUAL ASSAULT

---

This document will provide information on a **NEW Policy at your institution** regarding:

<b>WHO</b>	Sexual assault victims/survivors
<b>WHAT</b>	Universal offering of HIV Post-Exposure Prophylaxis (HIV PEP) medications
<b>WHERE</b>	Ontario, Canada (at Sexual Assault/Domestic Violence Treatment Centres – ‘SATCs’)
<b>WHEN</b>	Starting April 1, 2007
<b>WHY</b>	NEW Program to help prevent HIV, funded by the Ministry of Health and Long-Term Care

---

## Universal HIV PEP Program at a Glance

- ✓ All patients presenting to an Ontario SATC to receive counselling about potential HIV risks
- ✓ All patients at any risk of HIV infection (known or unknown) to be offered HIV PEP
- ✓ HIV PEP to begin within 72-hours<sup>1</sup> of exposure (ideally, give 1<sup>st</sup> dose ASAP)
- ✓ HIV PEP to be prescribed for a period of 28-days<sup>1</sup>
- ✓ An intensive follow-up schedule to monitor drug therapy & assist patients who accept HIV PEP
- ✓ HIV PEP to be provided at no cost to patients

Your local SATC has established **HIV Expert consultation** opportunities

## Overview of the HIV PEP Regimen: Combivir® and Kaletra®

- ♦ 28-day Regimen: Combivir® (300 mg zidovudine and 150 mg lamivudine), 1 tablet orally BID + Kaletra® (200 mg lopinavir and 50 mg ritonavir), 2 tablets orally BID
- ♦ **NEW** Now using Kaletra® tablets *instead* of Kaletra® capsules
  - Pill burden, storage and food requirements are different
- ♦ Chosen regimen reduces the chance of resistance to HIV drugs
  - Minimal pill burden helps to facilitate adherence<sup>1</sup>
  - Ongoing follow-up counselling helps to ensure that medications are taken as prescribed
- ♦ Combivir® [DIN 02239213] is manufactured by GlaxoSmithKline
  - *Storage*: in a cool (15-30°C) dry place, protected from light
  - *Bottle size*: 60 tablets (30 day supply)
- ♦ Kaletra® [DIN 022285533] is manufactured by Abbott
  - *Storage*: in a cool (20-25°C) dry place, protected from light (excursions permitted to 15°-30°C)
  - *Bottle size*: 120 tablets (30 day supply)
- ♦ Both Combivir® and Kaletra® can be taken with or without food
- ♦ Kaletra® decreases effectiveness of the birth control pill
- ♦ No interaction with other common prophylaxes, including: cefixime, azithromycin, Plan B/Ovral®
- ♦ Potential to interact with other medications, including: prescriptions, OTC, herbals, illicit drugs
  - For more information, refer to product monographs
- ♦ Common side effects include: headache, nausea, vomiting, stomach pain, diarrhea and/or fatigue
- ♦ Majority of side effects are not serious and can be managed with common OTC remedies
  - \* *Headache*: ASA, acetaminophen, ibuprofen
  - \* *Nausea/Vomiting*: antiemetic
  - \* *Diarrhea*: eat low-fat, low-fibre food
  - \* *Fatigue*: rest, eat healthy, temporarily reduce responsibilities
  - \* *Fever*: acetaminophen
  - \* *Rash*: antihistamine, acetaminophen, antibiotic ointment, lanolin-based soap

- ♦ Reimbursement of HIV PEP medications: Bill to the SATC Cost-Centre (as done with other medications)

## Program Rationale: Why Offer HIV PEP?

- ♦ HIV PEP is recommended to prevent transmission of HIV following occupational and non-occupational exposures such as unprotected sexual activities and injection drug use<sup>1</sup>
- ♦ Ontario Ministry of Health and Long-Term Care endorses this program & fully funds HIV PEP medications through your local Sexual Assault/Domestic Violence Treatment Centre (SATC)
- ♦ Heterosexual transmission is increasing (1/3 of HIV-positive test reports in Canada, 2005)<sup>2</sup>
- ♦ Women are twice as likely as men to contract HIV during (vaginal) intercourse<sup>3</sup>
- ♦ 39% of Canadian women experience at least one incident of sexual assault since the age of 16<sup>4</sup>
- ♦ HIV transmission following sexual assault may be greater (than consensual sex) due to presence of blood, sexually transmitted infections (STI) in the assailant or victim and/or exposure to multiple assailants

## Evidence to Support Non-Occupational HIV PEP

- ♦ HIV PEP is widely used in occupational exposure & mother-to-child transmission settings<sup>1,5,6</sup>
- ♦ Difficult to study in non-occupational setting due to ethical concerns re: study design and sample sizes
- ♦ Efficacy studied in occupational exposure – taking HIV PEP reduced odds of HIV infection by 81%<sup>7</sup>
- ♦ Animal studies – early initiation of HIV PEP is more effective in preventing HIV infection<sup>1,6,8,9</sup>
- ♦ Efficacy studied in mother-to-child transmission – a combination of pre-exposure and post-exposure prophylaxis for the neonate reduces HIV transmission by up to 2/3<sup>1,6,10,11,12</sup>
- ♦ Guidelines for the provision of HIV PEP following sexual assault have been developed and implemented in multiple North American and European jurisdictions<sup>6,13,14,15,16,17</sup>
- ♦ High HIV PEP uptake & completion rates captured in an evaluation of Ontario's universal HIV PEP program (2003-2005) indicate a clear demand for this program

## Assessing HIV Risk

- ♦ When the risk of transmission is unknown, it cannot be assumed as zero
- ♦ Considerations in estimating the probability that an assailant is HIV-positive: local HIV seroprevalence; potential to belong to high-risk group (e.g., IVDU, MSM, ex-prisoner, from country with high rates of HIV)
- ♦ 'Universal' Offering = HIV PEP is accessible to all patients at any risk of HIV

## Weighing Risks and Benefits: HIV and HIV PEP

- ♦ Potential benefits of HIV PEP are measured by balancing anticipated efficacy against individual health risks
- ♦ Risk of HIV = Risk of HIV-positive assailant + Type of exposure (anal, vaginal or oral – risk increases with physical trauma, presence of blood, STIs, multiple assailants, multiple receptive sites)
- ♦ Risks associated with HIV PEP – Potential of adverse effects (rare in literature); Potential development of drug resistance, especially if adherence is poor (rare due to combination ART therapy)<sup>1</sup>
- ♦ HIV PEP does not prevent all infections in occupational and perinatal settings. Similarly, it is not expected to have complete efficacy after non-occupational exposures, including sexual assault<sup>1</sup>
- ♦ Risks and benefits should be determined in conjunction with each patient on a case-by-case basis

<sup>1</sup> CDC. 2005. Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Non-occupational Exposure to HIV in the United States: Recommendations from the U.S. Department of Health and Human Services. *MMWR*. 54(RR-2): 1-20.

<sup>2</sup> Public Health Agency of Canada. 2006. *HIV and AIDS in Canada: Surveillance Report to December 31, 2005*. Surveillance and Risk Assessment Division, Centre for Infectious Disease Prevention and Control

<sup>3</sup> European Study Group. 1992. Comparison of female to male and male to female transmission of HIV in 563 stable couples. *BMJ*. 304: 809-13.

<sup>4</sup> Federal/Provincial/Territorial Ministers Responsible for the Status of Women. 2002. *Assessing Violence Against Women: A Statistical Profile*.

<sup>5</sup> Grulich AE. 2003. Epidemiologically targeted post-exposure prophylaxis against HIV: An under-utilized prevention technology. *HIV Medicine*. 4: 193-4.

<sup>6</sup> 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.

<sup>7</sup> Cardo DM, Culver DH, Ciesielski CA, Srivastava PU, Marcus R, Abiteboul D, Heptonstall J, Ippolito G, Lot F, McKibben PS, Bell DM. 1997. A case-control study of HIV seroconversion in health care workers after percutaneous exposure. *New England Journal of Medicine*. 337(21): 1485-90.

<sup>8</sup> Tsai CC, Enau P, Follis KE, Beck TW, Benveniste RE, Bischofberger N, Lifson JD, Morton WR. 1998. Effectiveness of postinoculation (R)-9-(2-phosphorylmethoxypropyl) adenine treatment for prevention of persistent simian immunodeficiency virus SIV<sub>mac</sub> infection depends critically on timing of initiation and duration of treatment. *Journal of Virology*. 72: 4265-73.

<sup>9</sup> Otten RA, Smith DK, Adams DR, Pulliam JK, Jackson E, Kim CN, Jaffe H, Janssen R, Butera S, Folks TM. 2000. Efficacy of postexposure prophylaxis after intravaginal exposure of pig-tailed macaques to a human-derived retrovirus (human immunodeficiency virus type 2). *Journal of Virology*. 74: 9771-5.

<sup>10</sup> Connor EM, Sperling RS, Gelber R. 1994. Reduction of maternal-infant transmission of human immunodeficiency virus type 1 with zidovudine treatment. Pediatric AIDS Clinical Trials Group Protocol 076 Study Group. *New England Journal of Medicine*. 331(18): 1173-1180.

<sup>11</sup> Wade NA, Birkhead GS, Warren BL, Charbonneau TT. 1998. Abbreviated regimens of zidovudine prophylaxis and perinatal transmission of the human immunodeficiency virus. *NEJM*. 339: 1409-14.

<sup>12</sup> Sperling RS, Shapiro DE, Coombs RW. 1996. Maternal viral load, zidovudine treatment, and the risk of transmission of human immunodeficiency virus type 1 from mother to infant. *NEJM* 335: 1621-9.

<sup>13</sup> Wiebe ER, Comay SE, McGregor M, Ducceschi S. 2000. Offering HIV prophylaxis to people who have been sexually assaulted: 16 months' experience in a sexual assault service. *Canadian Medical Association Journal*. 162(5): 641-5.

<sup>14</sup> Non-occupational HIV PEP Task Force, Brown University AIDS Program, and the Rhode Island Department of Health. 2002. Non-occupational human immunodeficiency virus post-exposure prophylaxis guidelines for Rhode Island healthcare practitioners.

<sup>15</sup> New York State Department of Health AIDS Institute. 2004. HIV Prophylaxis Following Non-Occupational Exposure Including Sexual Assault.

<sup>16</sup> Myles JE, Bamberger J. 2001. Offering HIV Prophylaxis Following Sexual Assault: Recommendations for the State of California. Prepared for the Housing and Urban Health of the San Francisco Department of Public Health and The California HIV PEP after Sexual Assault Task Force in conjunction with The California State Office of AIDS.

<sup>17</sup> Massachusetts Department of Public Health. 2005. HIV Prophylaxis Following Non-Occupational Exposures Recommended Protocol Components.

---

---

For more information, visit: **[www.satcontario.com/HIVPEP/](http://www.satcontario.com/HIVPEP/)**