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

**WHO**  
Sexual assault victims/survivors

**WHAT**  
Universal offering of HIV Post-Exposure Prophylaxis (HIV PEP) medications

**WHERE**  
Ontario, Canada (at Sexual Assault/Domestic Violence Treatment Centres – ‘SATCs’)

**WHEN**  
Starting April 1, 2007

**WHY**  
*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-hours¹ of exposure (ideally, give 1st dose ASAP)
- HIV PEP to be prescribed for a period of 28-days¹
- 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 adherence¹
  - 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 02285533] 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
- 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 (½ of HIV-positive test reports in Canada, 2005)
- Women are twice as likely as men to contract HIV during (vaginal) intercourse
- 39% of Canadian women experience at least one incident of sexual assault since the age of 16
- 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
- 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%
- Animal studies – early initiation of HIV PEP is more effective in preventing HIV infection
- 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 7/3
- Guidelines for the provision of HIV PEP following sexual assault have been developed and implemented in multiple North American and European jurisdictions
- 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)
- 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
- Risks and benefits should be determined in conjunction with each patient on a case-by-case basis

For more information, visit: www.satcontario.com/HIVPEP/