Quick Fact Sheet for Pharmacists

HIV PEP FOLLOWING SEXUAL ASSAULT

This document will provide information on **Changes to the HIV PEP regimen at your institution** regarding:

WHO Sexual assault victims/survivors

WHAT HIV Post-Exposure Prophylaxis (HIV PEP) medications. The antiretroviral regimen for adults and children ≥ 12 years old and ≥ 35 kg has been changed to Tenofovir/emtricitabine (Truvada®) and Lopinavir/ritonavir (Kaletra®). ®). For patients who have health contraindications to Kaletra, Raltegravir (Isentress®) should be provided.

No change was made regarding the recommended antiretroviral regimens for pregnant women and children < 12 years old, < 35 kg or unable to swallow tablets. The recommended regimens remain Lopinavir/ritonavir and Zidovudine/lamivudine for pregnant women and Lopinavir/ritonavir, Lamivudine (3TC®) and Zidovudine (Retrovir®) for children. Insufficient data in pregnant women and children < 12 years old or < 35 kg precludes the use of Tenofovir/emtricitabine in these populations.

WHERE Across Ontario at Sexual Assault/Domestic Violence Treatment Centres (SA/DVTCs)

WHEN Starting Spring, 2012

WHY This modification is based on expert opinion and takes into consideration the favourable tolerability profile of Tenofovir/emtricitabine[1] in comparison to the previously recommended antiretroviral, Zidovudine/lamivudine (Combivir®).

Universal HIV PEP Program at a Glance

- ✓ All patients presenting to an Ontario SA/DVTC 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[2] of exposure (ideally, give 1st dose ASAP)
- ✓ HIV PEP to be prescribed for a period of 28-days [2]
- ✓ 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 SA/DVTC has established **HIV Expert consultation** opportunities

Overview of the HIV PEP Regimen: Truvada® and Kaletra®

- 28-day Regimen: Truvada® 300 mg tenofovir and 200 mg emtricitabine), 1 tablet orally once a day
  + Kaletra® (200 mg lopinavir and 50 mg ritonavir), 2 tablets orally BID
- Chosen regimen reduces the chance of resistance to HIV drugs
  - → Minimal pill burden helps to facilitate adherence[1]
  - → Ongoing follow-up counselling helps to ensure that medications are taken as

prescribed

- Truvada® (DIN 02274906) is manufactured by Gilead Sciences
  - → *Storage*: Store Truvada at room temperature 77°F (25°C), excursions permitted to 15–30 °C
  - → *Bottle size*: 30 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 Truvada® and Kaletra® can be taken with *or* without food
- Kaletra® decreases effectiveness ofhormonal contraceptives including pill, patch, and vaginal ring formulations
- 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, abdominal pain, insomnia, diarrhea and/or fatigue
- Majority of side effects are not serious and can be managed with common OTC remedies
- Reimbursement of HIV PEP medications: Bill to the SA/DVTC Cost-Centre

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 use1
- 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 (SA/DVTC)
- At the end of 2008, an estimated 65,000 Canadians were living with HIV. Women account for 22% of the national total at an estimated 14,300.[3]
- In 2009, there were 1,013 positive HIV tests in Ontario, accounting for 44% of the national total. Ontario has the highest incidence and prevalence of HIV in Canada.[3]
- For 2008, heterosexual transmission was responsible for 36% of newly infected cases. Given that an assault involving a male assailant and female survivor is the most common scenario seen by SA/DVTC staff, these demographics have important implications for the SA/DVTC client population.[3]
- Up to 1/3 of HIV positive individuals in Canada do not know their HIV status.[3]
- Women are twice as likely as men to contract HIV during (vaginal) intercourse[4]
- 39% of Canadian women experience at least one incident of sexual assault since the age of 16[5]
- 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

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-inmate, from

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http://www.sadvtreatmentcentres.net/en/hivpep.php

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)[2]
- Risks and benefits should be determined in conjunction with each patient on a case-by-case basis

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[1] Tosini W, Muller P, Prazuck et al. Tolerability of HIV postexposure prophylaxis with tenofovir/emtricitabine and lopinavir/ritonavir tablet formulation. AIDS 2010;24:2375-80.

[2] 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.

[3] Public Health Agency of Canada. 2009. *HIV and AIDS in Canada: Surveillance Report to December 31, 2009*. Surveillance and Risk Assessment Division, Centre for Infectious Disease Prevention and Control

[4] European Study Group. 1992. Comparison of female to male and male to female transmission of HIV in 563 stable couples. *BMJ*. 304: 809-13.

[5] Federal/Provincial/Territorial Ministers Responsible for the Status of Women. 2002. Assessing Violence Against Women: A Statistical Profile.

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