HIV PEP Program

Providing High-Quality HIV Care at

Ontario Sexual Assault / Domestic Violence

Treatment Centres

ONTARIO NETWORK of Sexual Assault/Domestic Violence Treatment CENTRES

This program was developed in collaboration with

Women's College RESEARCH INSTITUTE

Outline

- Rationale for HIV PEP program
- Background on HIV
- Introduction to the HIV PEP program
- HIV PEP Regimen: Combivir® and Kaletra®
- Assessing HIV risk
- Follow-up HIV counselling
- Importance of the HIV PEP program in your community
- Accessing more HIV PEP program information

HIV PEP Program Rationale

Need for Response to HIV Risk Post Sexual Assault

- 39% of Canadian women experience at least one incident of sexual assault since the age of 16 [1]
- Approximately 2,000 sexual assault victims/survivors present to Sexual Assault/Domestic Violence Treatment Centres (SATC) in Ontario each year
  - → Over 95% are women
- Women are twice as likely as men to contract HIV during (vaginal) intercourse [2]
- HIV transmission following sexual assault may be greater (than consensual sex) due to genital/rectal trauma and bleeding, exposure to multiple assailants, exposure through multiple receptive sites, and/or presence of STIs (in the assailant or victim)

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

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

HIV PEP in Other Exposures

- HIV PEP is widely used in other settings[1-3]
  - → Occupational exposure
  - → Mother-to-child transmission

1. 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.
2. Grulich AE. 2003. Epidemiologically targeted post-exposure prophylaxis against HIV: An under-utilized prevention technology. *HIV Medicine.* 4: 193-4.
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.

HIV PEP Recommended Post Sexual Assault

- HIV PEP is recommended to prevent transmission of HIV following occupational and non-occupational exposures such as:
  - → Unprotected sexual activities
  - → Injection drug use

1. 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.

HIV PEP in Other Jurisdictions

- Guidelines for the provision of HIV PEP following sexual assault have been developed and implemented in multiple North American and European jurisdictions
  - → **Europe** [1] : Austria, Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Portugal, The Netherlands, United Kingdom, Slovenia, Spain, and Switzerland
  - → **Canada**: British Columbia [2]
  - → **United States**: Rhode Island [3], New York [4], California [5], Massachusetts [6]

1. 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
2. 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.
3. 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.
4. New York State Department of Health AIDS Institute. 2004. HIV Prophylaxis Following Non-Occupational Exposure Including Sexual Assault.
5. 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.
6. Massachusetts Department of Public Health. 2005. HIV Prophylaxis Following Non-Occupational Exposures Recommended Protocol Components.

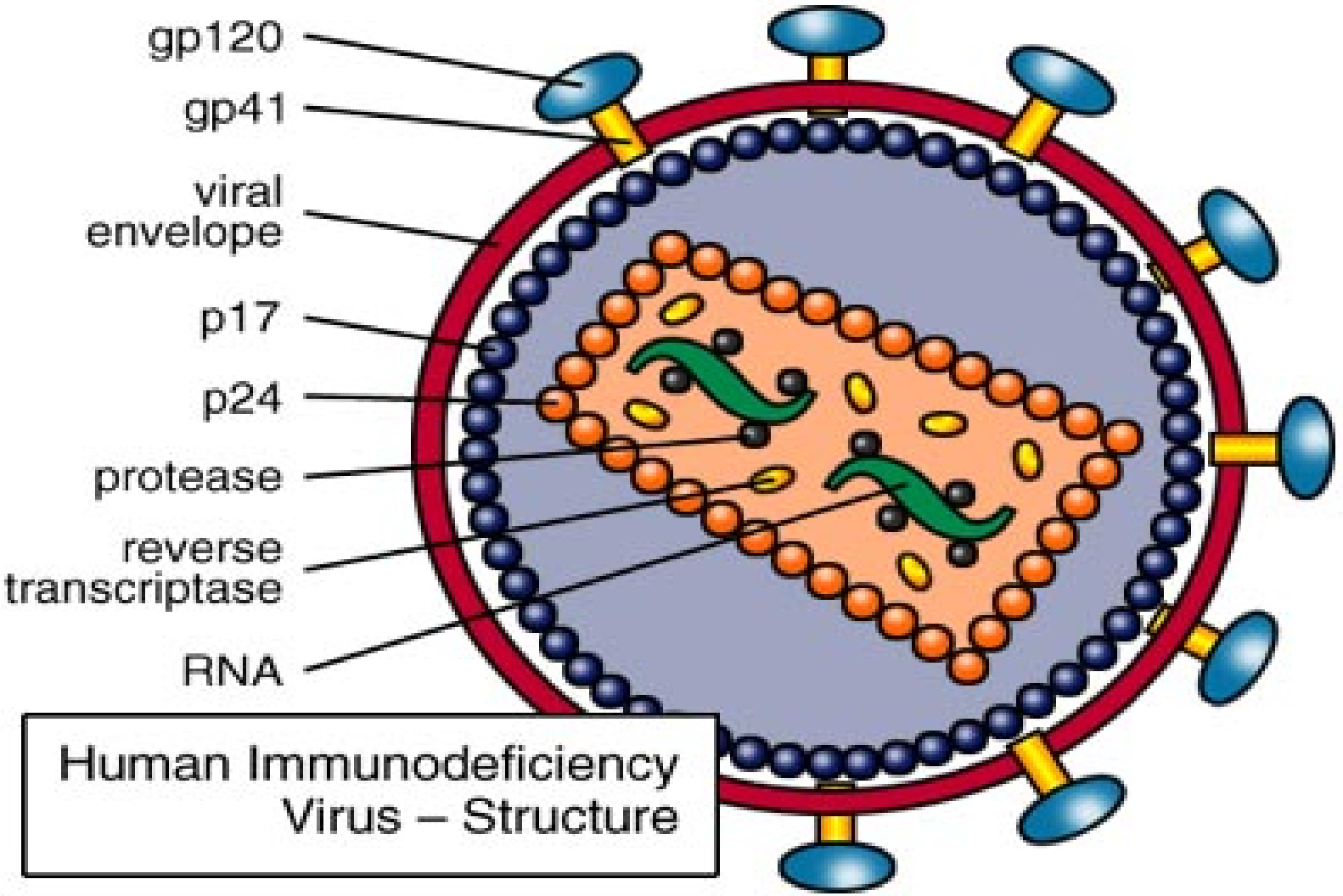
Background on HIV

ONTARIO
NETWORK
of
Sexual Assault/
Domestic Violence
Treatment
CENTRES

HIV Virology

- Different types of HIV
  - → HIV-1 & HIV-2 (*concentrated in Western Africa*)
- Different clades of HIV-1 (*A, B, C, D, E, F, G, K and O*)
  - → Clade B in North America
- HIV is an RNA virus (2 strands of RNA)
- HIV is a retrovirus
  - → Replicative enzyme = reverse transciptase
- Other important components
  - → Envelope – gp160 = gp120 + gp41
  - → Capsid – p24 antigen
  - → Enzymes – protease & integrase

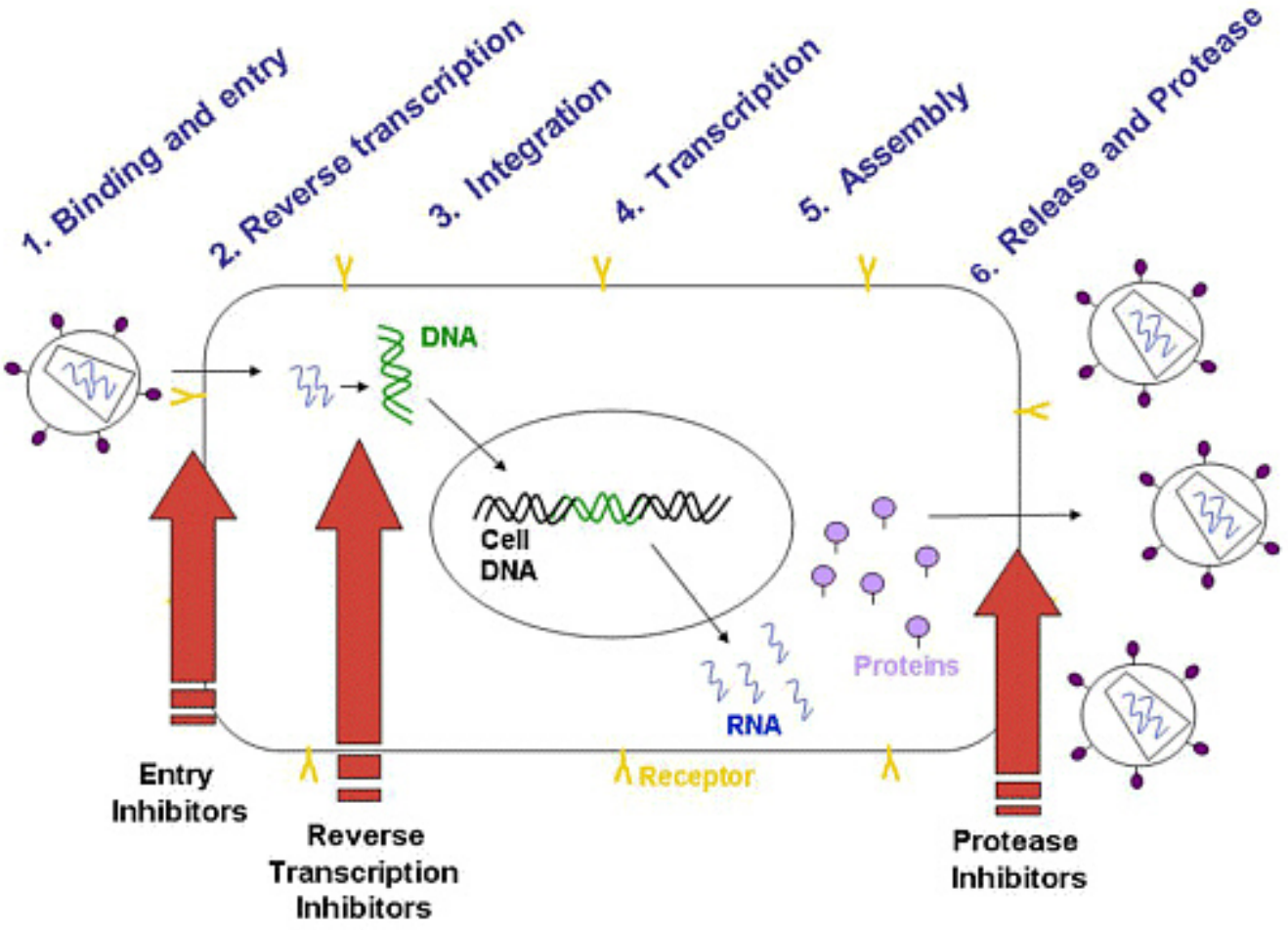
HIV Virus Structure



HIV Replication

- After initial infection → *immediate replication*
- 10 X 10^9 new viral products produced *each day*
- HIV binds to CD4 receptor on macrophages and CD4 T lymphocytes via gp120
- Co-receptor also needed – CXCR4 or CCR5

HIV Life Cycle



HIV Transmission

- A person infected with HIV carries the virus in body fluids, such as:
  - Blood
  - Semen or vaginal secretions
  - Breast milk
- The virus is transmitted when HIV-infected fluids enter the bloodstream of another person
- Transmission can occur through:
  - The mucus membrane linings of the vagina, rectum, mouth, or the opening at the tip of the penis
  - Intravenous injection with a syringe
  - Through a break in the skin, such as a cut or sore
- HIV is typically transmitted through **unprotected** sexual intercourse (oral, vaginal or anal), with someone who is HIV-infected, sharing needles/syringes with someone who is HIV-infected, or infection during pregnancy, childbirth, or breast-feeding (mother-to-infant transmission)

Increased Risk of HIV Transmission

- Risk of HIV infection following exposure is dependent upon the type of exposure itself, but also on a number of co-factors, such as:
  - Infectivity of the source (*high plasma viral load increases risk*)
  - Presence of ulcerations (open sores) on the genitals (**sexual exposure**)
  - Presence of sexually transmitted infections (STI) or bleeding (*STIs increase risk by 2-5x*, WHO, 2004). (**sexual exposure**)

- "*HIV Risk Assessment*" (Slides 33 – 36), outlines this continuum of HIV risk and identifies the various factors that increase risk within the context of sexual assault

Preventing HIV Infection

- Treatment for HIV infection: antiretrovirals
  - 4 classes: Nucleoside Reverse Transcriptase Inhibitors (NRTI), Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI), Protease Inhibitors (PI), Fusion inhibitors
  - 3 drugs from 2 classes typically used
- HIV PEP – given to *prevent* HIV infection
  - 28-day treatment of antiretroviral drugs taken twice a day
- Recall the HIV life cycle
  - Through the reverse transcription – integration – transcription process, HIV binds with cell DNA, the altered virus then releases to multiply
    - Fusion inhibitors block entry of the virus
    - NRTIs & NNRTIs block reverse transcription
    - PIs block assembly of the virus

HIV in Canada

- HIV is a growing issue in Canada
  - → Total number of people in Canada living with HIV/AIDS infection estimated to be 56,000 (2002)
  - → Total estimated new infections (incidence) in 2002 between 2,800 and 5,200

- 95% of reported HIV and AIDS diagnoses in Canada are in the provinces of Ontario, Quebec, British Columbia and Alberta
  - → Over 85% of Canada's population resides in these four provinces

Public Health Agency of Canada. May 2005. *HIV/AIDS EPI Updates*. Surveillance and Risk Assessment Division, Centre for Infectious Disease Prevention and Control, Public Health Agency of Canada.

Shifting Demographics

- Patterns of HIV transmission are currently shifting
  - → Although men who have sexual contact with men (MSM) account for the largest proportion of positive HIV test reports (43.5% in 2005)…
  - → Heterosexual transmission is increasing (30.9% of HIV-positive test reports in Canada, 2005) [1]

1. 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

Introduction to the HIV PEP Program

ONTARIO
NETWORK
of
Sexual Assault/
Domestic Violence
Treatment
CENTRES

HIV PEP Program History

- **1999**: Need for prophylaxis identified; Ontario Network of SATCs requested funding for HIV PEP medications from the Ministry of Health and Long-Term Care (MOHLTC)
- **2002**: MOHLTC funded the HIV PEP Study to determine feasibility of HIV PEP program
- **September 10, 2003 – January 31, 2005**: Data were collected on 1,103 consecutive sexual assault victims/survivors presenting to 24 participating SATCs
- **December 21, 2005**: Recommendations for an ongoing HIV PEP program were submitted to the MOHLTC; Findings indicated that a universal HIV PEP program:
  - → Was well-received and appreciated by sexual assault victims/survivors
  - → Enabled Health Care Providers to effectively support all clients at risk of HIV acquisition in their HIV PEP decision-making
  - → Improved the quality of sexual assault care in Ontario

HIV PEP Program Today

- **February 2006**: CIHR funded a 1-year Knowledge Exchange grant that is developing Knowledge Transfer (KT) Tools to assist the Ontario Network of SATCs in sustaining a standardised HIV PEP program and will support Ontario's HCPs in providing high-quality HIV care to Ontario's sexual assault victims/survivors. KT Tools include:
  - → Updated & revised HIV PEP program materials
  - → Targeted information packages
  - → Online information & education packages
  - → Targeted education & outreach strategies

- **August 2006**: MOHLTC committed  to providing ongoing base funding to Ontario's 34 SATCs to support the universal offering of HIV PEP medications

HIV PEP Program Guidelines

- All clients to receive counselling about potential HIV risks;
- All clients at any risk of HIV infection (known or unknown) to be offered HIV PEP;
- HIV PEP to begin within 72-hours of exposure;
- HIV PEP to be prescribed for a period of 28-days;
- An intensive follow-up schedule to assist clients who choose the prophylactic drugs to cope with side effects and complete the medication course; and,
- HIV PEP to be provided at no cost to clients.

Drug Funding

- Presently
  - → HIV PEP medications dispensed by SATCs are reimbursed monthly through claim submissions to the Ontario Network of SATCs Provincial Coordinator, Sheila Macdonald
- Starting April 1, 2007
  - → HIV PEP funding will flow through the LHINs
  - → Each SATC will be allocated annual funds for purchasing HIV PEP medications

HIV PEP Regimen:

Combivir® & Kaletra®

ONTARIO
NETWORK
of
Sexual Assault/
Domestic Violence
Treatment
CENTRES

Drug Regimen

- Daily HIV PEP dose:
  - → Combivir® (300 mg zidovudine & 150 mg lamivudine), 1 tablet orally BID
  - → Kaletra® (200 mg lopinavir & 50 mg ritonavir), 2 tablets orally BID
- The course of HIV PEP therapy is 28 days
- Schedule for the provision of HIV PEP:
  - → *Initial Visit:* 5-day "Starter Kit" (10 tablets of Combivir® + 20 tablets of Kaletra®)
  - → *1st Follow-up:* 10-day Follow-up Kit (20 tablets of Combivir® + 40 tablets of Kaletra®)
  - → *3rd Follow-up:* 7-day Follow-up Kit (14 tablets of Combivir® + 28 tablets of Kaletra®)
  - → *4th Follow-up:* 6-day Follow-up Kit (12 tablets of Combivir® + 24 tablets of Kaletra®)

Paediatric Drug Regimen

- Children ≥ 12 years of age AND ≥ 50 kg.
  - → Prescribe adult HIV PEP regimen (Combivir ® and Kaletra ®)

- Children < 12 years of age AND < 50 kg.
  - → Determine the drug dosage using the paediatric dosing charts:
    - ✳ Zidovudine & Lamivudine (components of Combivir ®)
    - ✳ Lopinavir & Ritonavir (components of Kaletra®)
  - → *See "Paediatric Dosing Charts"*
    Appendix 1C, Medical Guidelines

About Combivir® & Kaletra®

- Combivir®
  - → Contains 2 Reverse Transcription Inhibitors in one pill
    - ✳ AZT & 3TC
  - → Well tolerated – main side effect: headache, nausea, fatigue
  - → Serious side effect: anemia from AZT
- Kaletra®
  - → Contains 1 Protease Inhibitor with ritonavir to boost the level of the drug & maximise its efficacy
  - → Well tolerated – main side effect: diarrhea

Storage & Dispensing Info

- Storage
  - → Kaletra® - store in a cool (20°- 25°C) dry place, protected from light
  - → Combivir® - store in a cool (15 - 30°C) dry place

- Bottle sizes:
  - → Combivir® - 60 tablets per bottle (30 day supply)
  - → Kaletra® - 120 tablets per bottle (30 day supply)

- Food requirements:
  - → Both Combivir® and Kaletra® can be taken with *or* without food

Health Contraindications to HIV PEP

- Combivir® is contraindicated in clients who have:
  - Taken myelosuppressive or hemotoxic drugs within two weeks of starting PEP drugs;
  - A history of bone marrow insufficiency or severe anemia; and/or
  - Acute pancreatitis

- Kaletra® is contraindicated in clients with:
  - Acute or advanced liver failure

Drug Contraindications to HIV PEP

- Combivir® and Kaletra® may potentially interact with other medications, including:
  - → Prescriptions
  - → Over the counter medications
  - → Herbals
  - → Illicit drugs

(*Full list of contraindicated drugs available*)

Pregnancy & HIV PEP

- Antiretroviral drugs are potentially teratogenic in the first trimester of pregnancy
  - → HIV PEP is often avoided during this period

- However, if a woman is at increased-risk of HIV transmission, the risk of transmission to the fetus is very high during seroconversion
  - → Giving antiretroviral drugs in this scenario outweighs the risk of teratogenesis

- The decision to take HIV PEP during pregnancy should be made by the client, in consultation with an HIV Expert

Assessing HIV Risk

Time Since Exposure

- HIV PEP must be initiated within in 72-hours of exposure
  - → HIV replicates at an accelerated rate
  - → IF the virus has been transmitted, initiating HIV PEP > 72 hours post-exposure may not aid in halting replication of the virus

If > 72-hours since assault by a known HIV-positive assailant

  - → Refer the client to an HIV expert immediately – anti HIV therapy may be initiated as early treatment for acute HIV infection

- For all other clients presenting > 72 hours post-exposure
  - → An immediate HIV test and follow-up HIV testing at 4-6 weeks, 3 and 6 months post-assault is recommended

HIV Risk Assessment (1)

1. Determine HIV PEP Eligibility

No Risk	▪ NO penetration (anal, vaginal or oral) ▪ NO contact with assailant body fluid (e.g., blood; ejaculate)	+	ANY Assailant	**DO NOT Offer** HIV PEP
At Risk	▪ ANAL penetration (*Suspected, partial, or completed*) ▪ VAGINAL penetration (*Suspected, partial, or completed*) ▪ ORAL penetration (*Suspected, partial, or completed*) ▪ Contact with assailant body fluid (e.g., blood; ejaculate) via mucous membrane, non-intact skin or bite ▪ Unknown exposure (e.g., drug-assisted)	+	ANY Assailant	**Offer HIV PEP** COMBIVIR® & KALETRA® (BID) Provide counselling and education

HIV Risk Assessment (2a)

2. Weigh Client HIV Risks (case-by-case assessment)

*Two sets of factors must be considered when assessing HIV risk: **a) Exposure Risk Factors**; b) Assailant Risk Factors*

a) Exposure Risk Factors

* Anal penetration (*Suspected, partial, or completed*)
* Vaginal penetration (*Suspected, partial, or completed*)
* Anal, vaginal or oral injuries
* Blood in the anus, vagina or mouth
* Presence of sexually transmitted infections
* Presence of ulcerations (open sores) on the genitals
* Assault by multiple assailants
* Multiple receptive sites

IF any of these factors were present during the assault, **HIV risk is INCREASED**

* Oral penetration only (NO vaginal OR anal penetration)
* Contact with assailant body fluid only (e.g., blood; ejaculate) via mucous membrane, non-intact skin or bite
* No ejaculation
* Condom use

These factors may **DECREASE HIV risk** [1]

[1] **NOTE**: These factors are often difficult to assess in cases of sexual assault, as victims/survivors may not know if the assailant ejaculated or whether condoms were used properly or at all. Therefore, caution should be used when considering them in the risk assessment. Unless no penetration occurs, **these factors only decrease the risk and do not make it zero.**

HIV Risk Assessment (2b)

2. Weigh Client HIV Risks (case-by-case assessment)

Two sets of factors must be considered when assessing HIV risk: a) Exposure Risk Factors; b) Assailant Risk Factors

b) Assailant Risk Factors

b) Assailant Risk Factors

* Assailant known to be HIV-positive
* Assailant known or suspected to have HIV risk factors

HIV Risk Factors:

* Has Hepatitis C
* Intravenous drug user
* Man who has sex with men
* From a country with an HIV prevalence rate greater than 5% (e.g., certain countries in Sub-Saharan Africa)
* Has numerous sexual partners
* Has a sexually transmitted infection
* Engages in prostitution or trades sex for money/drugs
* Has sex with known or suspected HIV-positive people
* Has prior convictions for sexual assault
* Has been in prison

IF any of these factors are known or suspected,

HIV risk is INCREASED

Per incident probabilities of HIV Transmission

EXPOSURE TYPE	RISK OF HIV TRANSMISSION *(HIV-positive source)*
Non-Sexual Transmission	
Blood Product	1:1.1 (90%)
Needlesharing in IV drug use	1:149 (0.67%)
Needlestick injury	1:300 (0.3%)
Sexual Transmission (unprotected)	
Receptive anal intercourse *(Penetration by a penis)*	1:200 (0.5%)
Insertive anal intercourse *(Penetrating with the penis)*	1:1,538 (0.065%)
Receptive vaginal intercourse *(Penetration by a penis)*	1:1,000 (0.10%)
Insertive vaginal intercourse *(Penetrating with the penis)*	1:2,000 (0.05%)
Receptive oral sex *(Penetration by a penis)*	1:10,000 (0.01%)*
Insertive oral sex *(Penetrating with the penis)*	1:20,000 (0.005%)*

* Rates of oral sex refer only to oral penetration by penis (not oral/vaginal contact, which is a negligible risk unless blood is present)
Source: Centres for Disease Control, January 2005

Number & Prevalence of HIV-positive residents 18 years and older in Ontario, 2006

	MALES			FEMALES		
Region	**HIV Number**	**Population**	**HIV Prevalence**	**HIV Number**	**Population**	**HIV Prevalence**
Northern	430	402,425	0.107%	190	407,834	0.047%
Ottawa	2,200	407,879	0.539%	570	421,709	0.135%
Eastern	460	405,709	0.113%	110	413,155	0.027%
Toronto	13,500	1,273,971	1.060%	1,780	1,339,508	0.133%
Central East	1,420	1,691,460	0.084%	310	1,712,104	0.018%
Central West	1,530	1,168,692	0.131%	320	1,192,830	0.027%
Southwest	1,130	777,450	0.145%	300	792,621	0.038%
Total Ontario	**20,670**	**6,127,586**	**0.337%**	**3,580**	**6,279,761**	**0.057%**

Source: Robert Remis, Ontario HIV Epidemiologic Monitoring Unit, Department of Public Health Sciences, University of Toronto, 2006.
2004 population estimates provided by Health Data and Decision Support Unit (HDDSU), Knowledge Management Branch, Ontario Ministry of Health and Long-Term Care

For Example Assessing HIV Risk

The Scenario

- A 19-year-old woman arrives with a uniformed police officer at the emergency department at 1:00pm
- She has been sexually assaulted by an unknown man earlier that day (at approximately 6:00am)
- She discloses that she was orally and vaginally penetrated and that during the oral assault, no condom was used and no ejaculation occurred. She is unsure if a condom was used or if the assailant ejaculated during the vaginal assault
- Multiple bruising is present on her inner thighs

For Example Assessing HIV Risk

- Time since exposure: 7 hours
  - ✓ Less than 72 hours – continue HIV risk assessment

- HIV PEP eligibility: oral penetration + vaginal penetration
  - ✓ At Risk – eligible to be offered HIV PEP

- Case-by-case assessment: *Assailant risk factors – unknown; Exposure risk factors – multiple receptive sites*
  - ✓ HIV risk is increased – weigh risks / benefits with client

For Example Assessing HIV Risk

Considerations

- Does the client currently take any medications (including OTC, herbals, and/or illicit/street drugs)?
- Does the client use the birth control pill?
- Could the client be pregnant?
- Does the client have any existing concerns regarding sexually transmitted infections and/or HIV?

Consulting with an HIV Expert

- HIV Experts are available for consultation during business hours, when needed
  - → *Local HIV Expert contact info is available via your SATC Coordinator*

- When to consult with an HIV Expert
  - → Assailant known to be HIV-positive
  - → Contraindications to HIV PEP exist (health and/or drug contraindications)
  - → Client is pregnant
  - → Client is a child under the age of 12 years
  - → Client's baseline HIV test returns positive
  - → The client currently taking HIV PEP and having adherence difficulty

Follow-up HIV Counselling

Follow-up Care for Clients Specific Issues

In addition to general emotional support:

- Managing HIV PEP side effects
  - → Majority of the side effects to Combivir® and Kaletra ® are not serious
  - → Most common include headache, nausea/vomiting, stomach pain, diarrhea and/or fatigue
  - → Usually manageable with common over-the-counter remedies, if required (e.g. calcium like TUMS for diarrhoea)
  - → Usually go away after 1-2 weeks
- Contraception
  - → Kaletra® can decrease the effectiveness of long-term use birth control pills, so a barrier form of contraceptive (e.g., condom) should be used
- Pregnancy
  - → 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, so precautions to avoid pregnancy should be taken
- HIV Testing
  - → Recommended at 4-6 weeks, 3 and 6 months post-assault

Importance of the HIV PEP Program in Your Community

ONTARIO NETWORK of Sexual Assault/ Domestic Violence Treatment CENTRES

Addressing HIV Concerns

- Fear of HIV infection is common among sexual assault victims/survivors, post-assault

- The HIV PEP program offers counselling and medications that can concretely address these fears

  → Experienced staff help to support HIV PEP decision-making and to support sexual assault victims/survivors throughout their course of HIV PEP therapy

Providing High-Quality Care

- HIV PEP medications are available at no cost to sexual assault victims/survivors
- Flexibility of the HIV PEP program allows diverse sexual assault victim/survivor needs to be met
  - → Services are tailored on a case-by-case basis
- Increased follow-up services enhance support to clients taking HIV PEP
- HIV counselling engages clinician-client discussion
- Guidelines enable standardisation of HIV care across the province

Your Role in HIV PEP Care

- You are key in making information on the HIV PEP program available those accessing your service
- You can help sexual assault victims/survivors address their HIV concerns by providing them with information on:
  - → The HIV PEP program
  - → The local Sexual Assault/Domestic Violence Treatment Centre *(See list of SATC locations & information)*

Accessing More HIV PEP Program Information

ONTARIO NETWORK of Sexual Assault/ Domestic Violence Treatment CENTRES

How can I get more info?

- More information on the HIV PEP program is available at www.womensresearch.ca/programs/HIVPEP.php
- Contact Sheila Macdonald, Provincial Coordinator of the Ontario Network of Sexual Assault/Domestic Violence Treatment Centres
  - → sheila.macdonald@wchospital.ca
  - → 416.323.6400 ext. 4472
- *Pamphlets about the HIV PEP program are available for your clients! Contact Sheila Macdonald.*

Thank you!

This material is adapted from documentation developed for the Ontario HIV PEP Study (2003-2005), funded by the Ontario Women's Health Council. Revision of HIV PEP program materials has been funded by a Knowledge Transfer grant from the Canadian Institutes of Health Research. The Ontario Network of Sexual Assault/Domestic Violence Treatment Centres acknowledges the contributions of the Women's College Research Institute, the KTA project Advisory Committee, and each regional SATC that assisted in the refining HIV PEP program materials.