BRITISH COLUMBIA
CENTRE *for* EXCELLENCE
in HIV/AIDS

GUIDANCE FOR THE USE OF POST-EXPOSURE PROPHYLAXIS (PEP) FOR THE PREVENTION OF HIV IN BRITISH COLUMBIA

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Providence HEALTH CARE
How you want to be treated.

Version 31 March 2020

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I INTRODUCTION

This guideline is intended to guide health care providers caring for persons who have experienced significant exposure to blood and/or body fluids in the work place or community setting. The risk of Human Immunodeficiency Virus (HIV) acquisition from a given exposure depends on the likelihood the source has transmissible HIV infection, and the biological risk of HIV transmission based on the exposure that has occurred.

This guideline is designed to deal specifically with exposures to HIV and is not applicable to other exposures such as viral hepatitis.

This guideline provides a framework for a program of expert advice and prompt antiretroviral post-exposure prophylaxis (PEP) for potential exposures to HIV.

The BC Centre for Excellence in HIV/AIDS (BC-CfE) provides publicly funded antiretroviral drugs for prophylaxis of HIV exposures where it is medically indicated with a favourable risk/benefit ratio. The risk of becoming infected with HIV (which is generally extremely low from a single event) needs to be weighed against the potential risk of taking PEP [1, 2]. A 28-day course of three-drug combination antiretroviral therapy is the current standard of care for PEP [1, 2]. Studies show that when antiretroviral therapy is offered in a timely manner (within 72 hours) after an HIV exposure, the risk of acquiring HIV decreases by approximately 80% [3].

The BC-CfE provides 5-day starter kits of antiretroviral PEP in all emergency rooms in BC, outpost nursing stations, provincial prisons, and several Vancouver primary care and sexual health clinics listed here: http://cfenet.ubc.ca/post-exposure-prophylaxis#sites. It is recommended that the 5-day starter kit be initiated within two hours and no later than 72 hours after the potential exposure event, if at all possible. The initial period of coverage can be used to seek more information to help assess the risk of the specific exposure and the need for continuing PEP. If needed, the remaining 23 days of treatment will be dispensed by the St. Paul's Hospital Ambulatory Pharmacy in consultation with a BC-CfE physician.

Inquiries about the PEP program should be directed to the **St. Paul's Hospital Ambulatory Pharmacy: 1-888-511-6222**.

The BC-CfE is funded by the BC-Ministry of Health.

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III GOAL

To **reduce the risk of HIV transmission** to persons following exposure to blood or body fluids. Health care providers caring for persons exposed to blood or body fluids should also assess the risk of exposure to other pathogens including hepatitis B and hepatitis C viruses, and manage patients for these potential exposures according to the recommendations of the BC Centre for Disease Control (http://www.bccdc.ca/health-professionals/clinical-resources/communicable-disease-control-manual).

Sexual exposures may also result in the transmission of other sexually transmitted infections (STIs), e.g. viral hepatitis, syphilis, chlamydia, gonorrhea. Guidelines for the managements of persons exposed to STIs are available from the BC Centre for Disease Control (http://www.bccdc.ca/health-professionals/clinical-resources/communicable-disease-control-manual).

For cases of sexual assault, refer to the BC Women's Sexual Assault Service for other important outcomes of consideration (http://www.bcwomens.ca/health-professionals/professional-resources/sexual-assault-service-resources) or the BCCDC Sexual Assault Decision Support Tool (http://www.bccdc.ca/resource-gallery/Documents/Communicable-Disease-Manual/Chapter%205%20-%20STI/CPS_noncertified_DST_DispensingProphlaxisPostSexualAssault.pdf).

IV DEFINITIONS

IV.1 Potential exposure to HIV

An event where blood or other potentially infectious body fluid (capable of transmitting HIV) from an infectious (or a potentially infectious) source person comes into contact with

- subcutaneous tissue (via percutaneous exposure, by either by a needlestick or a cut with a sharp object)
- mucous membranes (eye, mouth, nose, vaginal, or anorectal)
- non-intact skin
  - healing wound (<3 days old)
  - skin lesion causing disruption of the epidermis

IV.2 Infectious body fluids (capable of transmitting HIV)

- Blood
- Any body fluid visibly contaminated with blood
- Semen
- Vaginal/rectal secretions
- Cerebrospinal fluid (CSF); amniotic, pleural, pericardial, peritoneal and synovial fluids and inflammatory exudates
- Tissue or organs e.g. transplantation
- Breast milk

IV.3 Non-infectious body fluids (unless bloody)

(Not implicated in the transmission of HIV unless visibly bloody)

- Stool, urine, tears, saliva, nasal secretions, vomitus, sputum, sweat

IV.4 Infectious/potentially infectious source person

IV.4.1 Source person known to be HIV positive

- The risk of HIV transmission is directly related to the HIV viral load (level of HIV viral particles in the blood) of the source person.
- The risk is lower (and may be zero, depending on the type of exposure) if the HIV-positive source person is receiving effective antiretroviral therapy and has a consistently (i.e. in at least two consecutive measurements) undetectable plasma viral load (<40 copies/mL) [4-10].
- Given that this information may not be readily available in an emergency situation, to prevent delays in starting PEP, it is recommended that the 5-day starter kit be provided in all cases of significant exposure to infectious body fluid from an HIV positive source person. The need for continuation of PEP will be reassessed by the BC-CfE physician on call for PEP.

IV.4.2 Source person at high risk of being HIV positive

- People who inject drugs (PWID)
- Men who have sex with men (MSM)
- Persons who have had multiple transfusions of blood or blood products (e.g. hemophiliacs) prior to November 1985
- Sexual partners of persons known to be HIV positive, or at high risk of being HIV positive

IV.4.3 Unknown source person(s)

- Will be assessed on a case-by-case basis by the St. Paul's Hospital Ambulatory Pharmacy (1-888-511-6222) in consultation with the BC-CfE physician on call for PEP.
- The risk of HIV infection is negligible from an abandoned needle outside the health care setting when there is no history of the origin of the needle or the time of its abandonment [11-13]. PEP is not recommended for needlesticks from an abandoned needle. If it is felt that exceptional circumstances could merit PEP for such an event (e.g. significant exposure in a setting where there is active injection drug use), the health care provider should contact the St. Paul's Hospital Ambulatory Pharmacy (1-888-511-6222) for expert advice.

V PROCEDURES FOR RISK ASSESSMENT

V.1 Introduction

If antiretrovirals are indicated for PEP, they are most effective if initiated **within two hours, and not more than 72 hours**, after exposure. Therefore, the health care provider should complete a risk assessment of the exposure **as soon as possible** after presentation.

The risk assessment should include:

- Assessment of the source person(s) if available, or based on information provided by the exposed person
- Assessment of the exposed person
- Assessment of the event and nature of exposure

The Risk Assessment Stratification Protocol (RASP) is a useful tool for estimating the risk of HIV infection for occupational exposures and to help guide decisions regarding the need for PEP based on the above information (https://www.mdcalc.com/hiv-needle-stick-risk-assessment-stratification- protocol-rasp) [14]. PEP is generally indicated if the risk level is 1/1000 (0.1%) or greater, and not indicated if the risk level is 1/100,000 (0.001%) or less. For intermediate levels of risk, PEP maybe considered on a case-by-case basis.

V.2 Assessment of exposed person

- Perform **baseline HIV serology** (HIV Ag/Ab testing) in all exposed persons not previously known to be HIV positive. If exposed person is known to be HIV positive, PEP is not indicated, and they should be referred for appropriate follow-up and treatment.

- If exposed person is at high risk of already being HIV positive, perform HIV point-of-care test, if available, and a standard 4th generation HIV Ag/Ab serology. If the exposed person is in a high risk group and history suggests potential acute HIV infection within the previous 6 weeks (symptoms[1] suggestive of acute HIV infection and potential high-risk exposure[s] during that time period), a nucleic acid amplification test (NAT) for HIV RNA is **not** routinely recommended. A standard 4th generation HIV Ag/Ab serology takes about 18 days to detect infection, and is known to identify most acute HIV infections. If history and symptoms[1] are suggestive of acute HIV infection within the previous 2 weeks, a NAT for HIV RNA is then recommended, because HIV RNA can be detected within 7 to 12 days after infection. This test can be arranged by contacting the medical microbiologist at the BC Centre for Disease Control (BCCDC) (*604-661-7033*). Consultation with a BC-CfE physician should be undertaken prior to proceeding with prophylaxis.

- PEP should not be withheld pending the results of the HIV Ag/Ab assay or the NAT.

- Perform baseline complete blood count (CBC) and differential, and creatinine with estimated glomerular filtration rate (eGFR) before starting PEP. If PEP is indicated, do not delay starting PEP while waiting for lab results.

- Perform serologic tests for hepatitis B virus (HBsAg, anti-HBc total, anti-HBs) and hepatitis C virus (anti-HCV). If anti-HCV is positive, test for HCV RNA (see http://www.bccdc.ca/health-professionals/clinical-resources/communicable-disease-control-manual/communicable-disease-control).

- Assess for other sexually transmitted infections (gonorrhea, chlamydia, syphilis), if appropriate (http://www.bccdc.ca/health-professionals/clinical-resources/communicable-disease-control-manual).

[1] Flu-like or mononucleosis-like illness, with or without a rash; see also http://cfenet.ubc.ca/sites/default/files/uploads/Guidelines/Management-of-Acute-HIV-Infections-[16-MAY-2018].pdf

- If exposed person is of child-bearing potential, determine whether they may be pregnant; if uncertain, do pregnancy test. If the exposed person is pregnant and the exposure is assessed to carry a significant risk of HIV transmission, contact the St. Paul's Hospital Ambulatory Pharmacy (1-888-511-6222) as soon as possible. If there has been a significant exposure, PEP should be started with the existing kit.

V.3 Assessment of event/exposure type (see Table 1 on page 9)

Some factors which can influence the risk of transmission include:

- In percutaneous exposure (via needle or other sharp object):
    - Solid device vs. hollow needle and gauge size
    - Visible blood on device and/or device previously in source's artery or vein
    - Depth of wound
    - Use of gloves by the exposed person
- In sexual exposures:
    - The presence of a sexually transmitted infection (especially genital ulcer disease) in either the source person or the exposed individual
    - Condom use
    - Degree of physical injury (e.g. mucosal or skin break) associated with the sexual act
- In other types of events (e.g. splashes):
    - Type of fluid
    - Volume of fluid
    - Duration of exposure

Table 1: Estimated risk of HIV transmission by exposure type from known HIV positive source person with detectable viral load

Exposure	Estimated Risk per 10,000 acts (95% Confidence Interval)	Estimated risk per act/ Event[1]
Hollow Bore Needlestick injury[2]	23 (0-46)	0.23%
Needle sharing – injection drug use	63 (41-92)	0.63%
Occupational Mucous membrane exposure[3]	9 (0.6-50)	0.09%
Penile-vaginal intercourse – risk to insertive partner	4 (1-14)	0.04%
Penile-vaginal intercourse – risk to receptive partner	8 (6-11)	0.08%
Anal intercourse (risk to insertive partner)	11 (4-28)	0.11%
Anal intercourse (risk to receptive partner)	138 (102-186)	1.38%
Oral intercourse (risk to either partner)	Low (0-4)	Low (<0.001%)

1. PEP is generally indicated if the risk level is 1/1000 (0.1%) or greater, and not indicated if the risk level is 1/100,000 (0.001%) or less.
2. Risk probably lower with cuts or punctures involving solid objects (vs. hollow bore needle)
3. Risk probably lower for exposures involving non-intact skin (vs. mucous membranes)
Transmission risk increased by higher plasma viral load or acute or late-stage HIV in the source person. Transmission risk in sexual exposures increased by genital ulcer disease, and decreased by condom use.

References:

Ippolito G, Puro V, de Carli G, and the Italian Study Group on Occupational Risk of HIV Infection. *Arch Intern Med* 1993; 153:1451-1458.
Patel P, Borkoff CB, Brooks JT, et al. Estimating per-act transmission risk: a systematic review. *AIDS* 2014; 28:1509-1519.
Baggaley RF, White RG, Boily M-C. Systematic review of orogenital HIV-1 transmission probabilities. *Int J Epidemiol.* 2008; 37:1255-65.

V.4 Assessment of source person

In all cases where the source person is known and available (either in person or by phone), the health care provider assessing the exposure event should seek verbal consent from the source person for the St. Paul's Hospital Ambulatory Pharmacist or BC-CfE physician to access to their medical records that are directly relevant to assessing the risk of HIV transmission to the exposed person (e.g. results of recent HIV Ag/Ab testing or HIV viral load testing if source is known to be HIV positive) and tailoring the PEP regimen if necessary (e.g. past and current antiretroviral use and results of drug resistance testing, if source is known to be HIV positive); and for this information to be shared with other health care providers directly involved in management of the event (e.g. the BC-CfE physician on call for PEP). Verbal consent for such access should be obtained directly from the source person and documented in the medical record of the exposed person.

The source person's medical records cannot be accessed in situations where the source person has not provided verbal consent for such access, and/or the consent has not been documented.

V.4.1 Source person known to be HIV positive

V.4.1.1 HIV positive source person not receiving antiretroviral therapy

- The risk of HIV transmission from an HIV positive source person not currently receiving antiretroviral therapy will depend on the type of exposure that has occurred. In general, significant exposures to blood or potentially infectious bodily fluids would warrant initiation of prophylaxis in this setting.

- If the source person consents to having his or her medical records accessed, contact the St. Paul's Hospital Ambulatory Pharmacy (*1-888-511-6222*) as soon as possible. However, start PEP immediately while making these arrangements or if access is not granted.

V.4.1.2 HIV positive source person receiving antiretroviral therapy

- The risk of HIV transmission from an HIV positive source person who is receiving antiretroviral therapy is reduced, in relation to the viral load of the source. If the source person's viral load is currently and consistently fully suppressed, the risk of transmission from a single sexual exposure is negligible [4-7]. Undetectable viral load in the source person may also reduce the risk of HIV transmission in percutaneous exposures involving blood-to-blood contact [8-10], but the risk may still be significant in such cases; persistence of HIV in latently infected cells has been demonstrated in patients receiving antiretroviral therapy, despite absence of cell-free virus in the peripheral blood (as measured by viral load) [1].

- If the source person consents to do so, blood work should be obtained in order to confirm ongoing viral load suppression.

- If the source person consents to having his or her medical records accessed, contact the St. Paul's Hospital Ambulatory Pharmacy (*1-888-511-6222*) as soon as possible. However, start PEP immediately while making these arrangements or if access is not granted.

V.4.2 Source person known but HIV status unknown

V.4.2.1 Source person available for HIV testing

- If the source person is available for interview, additional information about risk history can be obtained and permission for baseline testing can be requested to assist in determining the likelihood of HIV exposure. If the source person agrees, an HIV point-of-care test (if available) and a standard 4th generation HIV Ag/Ab serology can be performed at this time.

- If the source person's HIV test is negative, prophylaxis is not required. In circumstances where the source is known to be in a high risk group and has had symptoms[2] suggestive of acute HIV infection within the previous 6 weeks, a nucleic acid amplification test (NAT) for HIV RNA is **not** routinely recommended. Perform HIV point-of-care test, if available, and a standard 4th generation HIV Ag/Ab serology. The HIV point-of-care test typically detects an infection within >22 days, whereas a standard 4th generation HIV Ag/Ab serology takes about 18 days to detect infection, and is known to identify most acute HIV infections. If the source person's history and symptoms[2] are suggestive of acute HIV infection within the last 2 weeks, a NAT for HIV RNA is recommended, because HIV RNA can be detected within 7 to 12 days after infection. This test can be arranged by contacting the medical microbiologist at the BC Centre for Disease Control (BCCDC) (*604-661-7033*). Prophylaxis should be started or continued (if exposure type warranted initiation) until both results are confirmed to be negative.

- Ensure appropriate follow-up for the source person to obtain their test results through their family physician or other identified follow-up health care provider.

- RESULTS OF SOURCE TESTING CANNOT BE DISCLOSED TO THE EXPOSED INDIVIDUAL. THEY CAN BE INFORMED ONLY OF THE RECOMMENDATIONS FOR NEED FOR ONGOING PEP.

V.4.2.2 Source person not available for HIV testing

- When the source person is unavailable or declines HIV testing, the risk of HIV exposure can be roughly be estimated using community prevalence estimates of HIV within a particular risk group within British Columbia and the type of exposure that has occurred (see Appendix I, page 22).

- Groups considered to be at potentially higher risk for HIV infection are shown in section IV.4.2.

- In cases involving an exposure type associated with increased HIV transmission (see Table 1, page 9) and a source person belonging to a high-risk group, the exposed person should be offered PEP.

V.4.3 Unknown source person

In settings where the source identity is unknown, HIV risk may be inferred by the potential likelihood of HIV within the risk group of the source person, if known (See Appendix I, page 22).

[2] Flu-like or mononucleosis-like illness, with or without a rash; see also http://cfenet.ubc.ca/sites/default/files/uploads/Guidelines/Management-of-Acute-HIV-Infections-[16-MAY-2018].pdf

The risk of HIV infection is negligible from an abandoned needle outside the health care setting when there is no history of the origin of the needle or the time of its abandonment [11-13]. PEP is not recommended for needlesticks from an abandoned needle. If it is felt that exceptional circumstances could merit PEP for such an event (e.g. significant exposure in a setting where there is active injection drug use), the health care provider should contact the St. Paul's Hospital Ambulatory Pharmacy (1-888-511-6222) for expert advice.

VI SPECIMEN HANDLING AND MANAGEMENT OF TEST RESULTS

Specimens from the source and the exposed persons should be accompanied by the Management of Percutaneous or Permucosal Exposure to Blood and Body Fluid/Laboratory Requisition form, HLTH 2339 (https://www2.gov.bc.ca/assets/gov/health/forms/2339fil.pdf).

Specimens drawn from the source person should be clearly identified on the requisition as coming from a potential HIV exposure episode so rapid turnaround (24-48 hours) can be achieved by the laboratory. Direct communication with the laboratory is desirable. The specimens can be sent to:

- UBC Virology Laboratory at St. Paul's Hospital (*604-806-8420*)
- BCCDC Public Health laboratory (*1-877-747-2522 or 604-707-2819*)
- On Vancouver Island, send specimens to Victoria General Hospital laboratory (*250-727-4212*)

An on-call medical microbiologist is available after-hours to facilitate shipment, testing, and reporting of results (*604-661-7033*).

It should be made clear to the lab and to the exposed person who is to receive test results. The exposed person is entitled to know if continued prophylaxis is required or not; no information regarding the source person should be provided to the exposed person.

Ensure appropriate follow-up for the source person to obtain their test results through their primary care provider, admitting physician or other identified follow-up health care provider.

When the results of HIV testing are known, the risk assessment should be re-evaluated.

If the source person's HIV test result is negative, continued prophylaxis is not required. Third- and fourth-generation HIV tests, including point-of-care tests, currently in use in BC become positive a median of 18 days (range 17-22 days) after infection and have increased the diagnostic yield for early acute HIV [15-17].

VII MANAGEMENT RECOMMENDATIONS

A 28-day course of antiretrovirals is recommended for significant exposure to blood or other potentially infectious body fluids of a person known to be HIV positive or at high risk for HIV, when that exposure represents a substantial risk for transmission, and when the person seeks care within 72 hours of exposure [1, 2]. Management recommendations for potential HIV exposures can be summarized as follows.

Negligible risk of HIV transmission

Source person known to be HIV negative or at low risk of HIV

OR

Material to which exposure has occurred is a body fluid not known to transmit HIV (urine, nasal secretions, saliva, sweat, or tears if not visibly bloody)

OR

An event not known to transmit HIV (e.g. contact with intact skin; superficial scratches that do not bleed; bites unless there is blood in the mouth of the biter)

↓

PEP NOT recommended.

Consult with St. Paul's Hospital Ambulatory Pharmacy (*1-888-511-6222)* if an unusual exposure has occurred.

Significant risk of HIV transmission

Material to which exposure has occurred is blood or a potentially infectious body fluid capable of transmitting HIV (semen, vaginal secretions, or any body fluid that is visibly contaminated with blood)

AND

Percutaneous exposure,
mucous membrane or
non-intact skin exposure,
or sexual exposure (vagina or rectum)

AND

Source person is known to be HIV positive
or known to be at a high risk for HIV

↓

Initiate PEP starter kit:
Tenofovir DF 300 mg once a day
Lamivudine 150 mg twice a day
Raltegravir 400 mg twice a day

Arrange for follow-up with primary care provider who will consult the St. Paul's Hospital Ambulatory Pharmacy to evaluate need for full 28-day course of PEP

If uncertain whether to initiate PEP, consult the St. Paul's Hospital Ambulatory Pharmacy (*1-888-511-6222*).

VII.1 Management recommendations when risk of HIV transmission is negligible

- No PEP is recommended.
- The treatment of a high anxiety level in the exposed person is reassurance, counselling, and education, not antiretrovirals. PEP carries certain risks and should be provided for medical indications only.
- Anxiety in this situation can be extremely high and the exposed person should be counselled thoroughly by someone familiar with this type of event and, if necessary, referred for professional counselling.

VII.2 Management recommendations when risk of HIV transmission is significant

- Assess baseline risk of HIV in the exposed person and perform **baseline HIV Ag/Ab test**.
- Baseline lab work for PEP (CBC and differential, creatinine and eGFR), viral hepatitis (HBsAg, anti-HBc total, anti-HBs, anti-HCV) if appropriate, pregnancy (if appropriate), and other sexually transmitted infections (if appropriate). If anti-HCV is positive, test for HCV RNA (see http://www.bccdc.ca/health-professionals/clinical-resources/communicable-disease-control-manual/communicable-disease-control).
- Start PEP as soon as possible (within 72 hours, preferably within 2 hours).
- Patients must follow up with their primary care provider or designated alternate care provider (if no primary care provider is identified) as soon as possible (within the 5-day period of the starter kit) to arrange continuing PEP (if appropriate) and follow-up testing.
- The St. Paul's Hospital Ambulatory Pharmacy can be contacted (*1-888-511-6222*) by the primary care provider to evaluate need to receive the full 28-day PEP regimen based on results of any laboratory results that may have been requested at initial exposure.
- For individuals receiving 28 days of therapy, follow-up laboratory monitoring (CBC and differential, creatinine, eGFR) should be completed at weeks 2 and 4 of therapy if any abnormalities were detected at baseline.
- The St. Paul's Hospital Ambulatory Pharmacy can be contacted (*1-888-511-6222*) in cases of medication intolerance, toxicity, or anticipated suboptimal adherence for evaluation of adjustment of the PEP regimen.
- Patient information sheet and instruction form for medication renewal in the 5-day starter kit are to be delivered to the follow-up provider by the exposed person.
- All persons who have experienced a significant exposure, regardless of whether PEP is given, should be counselled regarding precautions to prevent potential HIV transmission to others. See Counselling Guidelines, Appendix II, page 23.

VII.2.1 PEP medications

The PEP starter kit consists of a 5 day supply of:

- Tenofovir DF: one tablet (300 mg) once a day
- Lamivudine: one tablet (150 mg) twice a day
- Raltegravir: one tablet (400 mg) twice a day

The medications in the PEP kit are provided as separate entities (rather than fixed dose combinations) to enable dose adjustments in cases where the exposed person is a child or has renal insufficiency. A full course of PEP is 28 days. The health care provider following the patient should contact the St. Paul's Hospital Ambulatory Pharmacy (*1-888-511-6222*) before the completion of the 5-day starter kit and prescribe an additional 23 days of PEP medication, if the BC-CfE physician agrees that continued PEP is appropriate based on the currently available information (which may include further information on the source's HIV status, viral load, antiretroviral

therapy, and/or HIV drug resistance, if the source person has agreed to have their medical records accessed).

If continued PEP is appropriate, the following medications will be prescribed for the next 23 days:

- Emtricitabine/tenofovir DF: one tablet (200 mg/300 mg) once a day (replaces tenofovir DF and lamivudine)
- Raltegravir: one tablet (400 mg) twice a day

The exposed person should be counselled regarding the change in medication which is being made to simplify the regimen. The medication change from lamivudine to emtricitabine is unlikely to affect tolerability. If suboptimal adherence is anticipated, contact the St. Paul's Ambulatory Pharmacy (*1-888-511-6222*) to discuss a once-daily regimen.

The BC-CfE physician may recommend additional modification of the regimen in the following situations:

- Significant intolerance, toxicity, or anticipated suboptimal adherence.
- Source on antiretroviral therapy with unsuppressed plasma viral load and/or has history of known or suspected resistance to any agents in the PEP regimen.
- If the exposed person is a child (see Table 2, page 18).
- If the exposed person is pregnant, contact the St. Paul's Hospital Ambulatory Pharmacy (1-888-511-6222) for advice. However, if a significant exposure has occurred, the existing kit should be given as soon as possible[3].

VII.2.2 Contraindications to PEP

A careful medication history (including prescription and non-prescription medications, supplements and alternative therapy) should be obtained and questions regarding drug interactions should be directed to the St. Paul's Hospital Ambulatory Pharmacy (*1-888-511-6222*).

Avoid or use with extreme caution in persons with **chronic renal insufficiency** (estimated glomerular filtration rate [eGFR] <50 mL/min). Specific cases should be discussed with a BC-CfE physician or St. Paul's Hospital Ambulatory pharmacist (*1-888-511-6222*).

VII.2.3 Potential Adverse Effects of PEP

Tenofovir DF is usually well-tolerated and side effects are generally mild. They may include headache, fatigue, nausea, diarrhea and gas [19, 20]. Rarely, patients have had kidney function changes when taking tenofovir DF and appropriate lab testing should be done. Close monitoring is advised in patients with a history of kidney disease, risk factors for kidney disease (e.g. diabetes, hypertension), or who are receiving concomitant medications with nephrotoxic potential (e.g. high dose non-steroidal anti-inflammatory drugs [NSAIDS]).

Lamivudine is usually well-tolerated in short-term therapy and side effects are rare. A reversible decrease in white blood cell count is the most common side effect but is very rare.

Emtricitabine is usually well-tolerated in short-term therapy. Side effects (such as rash, nausea, diarrhea, headaches) are rare.

Raltegravir is generally well-tolerated. Side effects are uncommon, usually mild, and can include

[3] Tenofovir DF, lamivudine, emtricitabine, and raltegravir are recommended antiretroviral agents both for treatment of HIV during pregnancy [18] and for PEP in pregnant persons [1, 2].

headache, insomnia, fatigue, dizziness, abdominal pain, myalgias, nausea, vomiting, and diarrhea [19, 20].

VIII FOLLOW-UP RECOMMENDATIONS

- Follow-up is required for persons having had a significant risk exposure to HIV, regardless of whether PEP is started.
- Follow-up should be done by the exposed person's primary care provider. If they do not have a primary care provider, identify an alternate provider for follow-up.
- For follow-up of exposure for persons at risk for hepatitis B and/or C, see http://www.bccdc. ca/resource-gallery/Documents/Guidelines%20and%20Forms/Guidelines%20and%20Manuals/Epid/CD%20Manual/Chapter%201%20-%20CDC/CPS_CDManual_BBFExpManage.pdf
- Follow-up testing should be performed according to the following schedule:
  - If PEP is started[4]:
    - Baseline: HIV Ag/Ab test
    - 2 and 4 weeks after exposure (while on PEP): CBC and differential, creatinine, eGFR, if any abnormalities were present on baseline testing
    - 3 and 6 weeks after end of PEP: HIV Ag/Ab test
    - 3 months after end of PEP: HIV Ag/Ab test
  - If PEP is not started despite being indicated (i.e. PEP not started due to patient preference or presentation >72 hours after a potentially significant risk exposure):
    - Baseline: HIV Ag/Ab test
    - 3 and 6 weeks after the exposure: HIV Ag/Ab test
    - 3 months after the exposure: HIV Ag/Ab test
  - In cases where PEP is not started because the risk of HIV transmission was estimated to be negligible, follow- up testing may still be considered, especially for events occurring in an occupational setting.

For recommendations regarding follow-up testing for hepatitis B and C, if appropriate, see the Management of Percutaneous or Permucosal Exposure to Blood or Body Fluid Letter for Follow- up Physician form, HLTH 2340 (http://www2.gov.bc.ca/assets/gov/health/forms/2340fil.pdf).

IX WORKSAFE BC CLAIMS FOR OCCUPATIONAL EXPOSURES

Determine if the incident occurred during work/at the workplace and if so, complete and submit WorkSafeBC Physician's Report (Form 8/11): https://www.worksafebc.com/en/resources/health-care-providers/forms/physicians-report-form-811?lang=en.

Ensure that the exposure is reported to the employer and properly documented. Adequate documentation including HIV testing is important if the worker becomes HIV positive. For the WorkSafeBC to accept a claim for seroconversion, the most likely cause must be the work exposure.

[4] PEP inhibits viral replication so neither HIV RNA nor p24Ag will be expressed and antibody will not be generated. Therefore, a potential false negative serology or RNA may result while on PEP. The drug wash-out period is estimated to be in the three week range; hence, serologic testing should be delayed until after PEP completion.

Test the exposed worker for HIV as soon as possible after the exposure, as described above.

PEP is not recommended for needlesticks from an abandoned needle outside a health care setting. If it is felt that exceptional circumstances could merit PEP for such an event (e.g. significant exposure in a setting where there is active injection drug use), the health care provider should contact the St. Paul's Hospital Ambulatory Pharmacy (1-888-511-6222) for expert advice.

The circumstances of the exposure must be investigated to identify causes and contributing factors and implement corrective actions, in order to prevent future exposures occurring in a similar manner.

X MANAGEMENT OF EXPOSURES IN CHILDREN

The risks of children being infected with HIV from accidental needlestick injuries [11-13], biting [21], or sexual assaults are very low. No data are available that show that PEP will decrease the risk of infection in children who sustain needlestick injuries or sexual assault.

PEP should be considered for children where the exposure is likely to have resulted in a transfer of potentially infectious body fluid to the recipient. In children, this would most commonly occur from blood or semen from a youth or adult who is known to be HIV positive or could potentially be HIV positive. PEP should be considered for children sustaining sexual assault resulting in vaginal or anal penetration.

PEP should only be considered for human bites in children that result in the skin being broken and when bleeding has occurred and there is blood in the mouth of the biter who is known to be HIV positive. The risk of HIV infection is negligible in bites from children. Should a child bite an HIV positive person, PEP may be considered if there is blood in the mouth of the child and there are areas of non-intact mucosa.

If required, PEP is recommended for a total of 28 days. Pediatric starter kits are not available. See dose modifications in Table 2, page 18.

Appropriate follow-up management of children should be made with either the family physician or a designate. The remaining 23-day supply of drugs should be ordered as soon as possible through the St. Paul's Hospital Ambulatory Pharmacy (1-888-511-6222).

Table 2: PEP dosing recommendations for children

Drug	Child's weight	Dose
Tenofovir DF 300 mg tablet[1] (≥ 2 years of age)[3]	8 to < 16 kg	75 mg (one quarter tablet) once daily
	16 to < 25 kg	150 mg (one half tablet) once daily
	25 to < 35 kg	225 mg (three-quarter tablet)
	≥ 35 kg	300 mg (one tablet) once daily
Lamivudine 150 mg tablet[2]	< 14 kg (and ≥ 4 weeks of age)	4 mg/kg/dose twice daily
	14 to < 20 kg	75 mg (one-half tablet) twice daily
	≥ 20 to < 25 kg	75 mg (one-half tablet) in a.m. and 150 mg (one tablet)
	≥ 25 kg	150 mg (one tablet) twice daily
Raltegravir 400 mg tablet (≥ 2 years of age)[3]	< 10 kg	8 mg/kg/dose twice daily
	10 to < 14 kg	100 mg (one-quarter tablet)
	14 to < 25 kg	200 mg (one-half tablet) twice daily
	≥ 25 kg	400 mg (one tablet) twice daily

1. Tenofovir DF tablet is difficult to split. Parents should get a pill splitter. The tablet may be crushed and mixed with a small amount of jam, yogurt or peanut butter to mask the bitter taste.
2. Lamivudine tablet can be crushed and mixed with food.
3. For children < 2 years of age, contact the on-call Pediatric Infectious Diseases specialist (604-875-2161) or the Oak Tree Clinic pediatrician (604-875-2250).

Children < 36 kg may be unable to swallow tablets or capsules. The tablets in the starter pack can be used to initiate therapy and then promptly consult with Oak Tree Clinic pharmacist (604-875-2212 extension 2) or pediatrician (604-875-2250).

References:

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Toronto General Hospital, University Health Network Immunodeficiency Clinic. HIV/HCV Drug Therapy Guide. http://app.hivclinic.ca/

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CONTACTS AND RESOURCES

- **St. Paul's Hospital Ambulatory Pharmacy** (general PEP inquiries)
  1-888-511-6222

- **BCCDC Public Health Laboratory**
  1-877-747-2522 or 604-707-2819

- **BCCDC Medical microbiologist on call** (re: HIV NAT in cases of suspected acute HIV; specimen shipping and handling, results reporting)
  604-661-7033

- **BCCDC Blood and Body Fluid Exposure Management** (October 2017)
  http://www.bccdc.ca/resource-gallery/Documents/Guidelines%20and%20Forms/Guidelines%20and%20Manuals/Epid/CD%20Manual/Chapter%201%20-%20CDC/CPS_CDManual_BBFExpManage.pdf

- **BCCDC Communicable Disease Control Manual;** Chapter 5 – Sexually Transmitted Infections; Guidelines for Testing, Fol- low up, and Prevention of HIV (October 2016).
  http://www.bccdc.ca/resource-gallery/Documents/Communicable-Disease-Manual/Chapter%205%20-%20STI/HIV_Guidelines_Testing_FollowUp_Prevention.pdf

- **BCCDC Sexual Assault Decision Support Tool** http://www.bccdc.ca/resource-gallery/Documents/Communicable-Disease-Manual/Chapter%205%20-%20STI/CPS_noncertified_DST_DispensingProphlaxisPostSexualAssault.pdf

- **BC-CfE Therapeutic Guidelines: Management of Acute HIV Infection**
  http://cfenet.ubc.ca/sites/default/files/uploads/Guidelines/Management-of-Acute-HIV-Infections-[16-MAY-2018].pdf

- **BC Treatment Guidelines, Sexually Transmitted Infections in Adolescents and Adults** (2014) http://www.bccdc.ca/ resource-gallery/Documents/Communicable-Disease-Manual/Chapter%205%20-%20STI/CPS_BC_STI_Treatment_Guide- lines_20112014.pdf

- **BC Women's Sexual Assault Service Resources**
  http://www.bcwomens.ca/health-professionals/professional-resources/sexual-assault-service-resources

- **Oak Tree Clinic, BC Women's Hospital and Health Centre**
  Pharmacist 604-875-2212 extension 2
  Pediatrician/ Infectious Disease specialist 604-875- 2250 or 604-875-2161

- **Risk Assessment Stratification Protocol (RASP)**
  https://www.mdcalc.com/hiv-needle-stick-risk-assessment-stratification-protocol-rasp

- **UBC Virology Laboratory**
  604-806-8420

- **Victoria General Hospital Laboratory**
  250-727-4212

APPENDIX I: RISK ASSESSMENT: ESTIMATED PROBABILITY OF HIV FOLLOWING A SINGLE EXPOSURE IN BRITISH COLUMBIA

	Source Person in Major Risk Group			Source Person Not Known to be in a Major Risk Group		
	Known HIV+	PWID	MSM	Biological Male	Biological Female	Unknown
Estimated probability of being HIV+	100%	13%	23%	0.009%	0.002%	0.006%
Estimated probability of seroconversion after sexual exposure[2]						
Penile-vaginal intercourse (risk to insertive partner)	0.04%	0.005%	0.01%	0.000004%	0.000001%	0.000002%
Penile-vaginal intercourse (risk to receptive partner)	0.08%	0.01%	0.02%	0.000007%	0.00002%	0.000005%
Insertive anal intercourse	0.11%	0.01%	0.025%	0.00001%	0.000002%	0.000007%
Receptive anal intercourse	1.38%	0.2%	0.3%	0.0001%	0.00003%	0.00008%
Oral sex[3]	0.01%	0.001%	0.002%	0.0000009%	0.0000002%	0.0000006%
Estimated probability of seroconversion after parental exposure[2]						
Percutaneous needle stick[4]	0.23%	0.03%	0.05%	0.00002%	0.000009%	0.00001%
Needle sharing injection drug use	0.63%	0.08%	0.14%	0.00006%	0.00001%	0.00004%
Occupational mucous membrane exposure[5]	0.09%	0.01%	0.02%	0.00001%	0.000002%	0.000005%

PWID, person who injects drugs; MSM, men who have sex with men

1. Based on Public Health Agency of Canada surveillance data 2014; Moore D et al., JAIDS 2016, 72: 87-95; Public Health Agency of Canada. I-Track: Enhanced Surveillance of HIV, Hepatitis C and associated risk behaviours among people who inject drugs in Canada. Phase 2 Report. Centre for Communicable Diseases and Infection Control, Infectious Disease Prevention and Control Branch, Public Health Agency of Canada; 2013.
2. Based on estimates for each exposure type from Patel P et al., AIDS 2014; 28:1509-1519 and Ippolito G et al., Arch Int Med 1993; 153:1451-1458.
3. Low risk for both receptive and insertive oral sex; 95% confidence interval around the estimate is 0-4 per 10,000 exposures [Patel P et al., AIDS 2014; 28:1509-1519]
4. Risk probably lower with solid object [Ippolito G et al., Arch Int Med 1993; 153:1451-1458.]
5. E.g. splashes to eyes, nose, mouth; risk probably lower with exposure to non-intact skin [Ippolito G et al., Arch Int Med 1993; 153:1451-1458.]

APPENDIX II: COUNSELLING GUIDELINES

While awaiting the test results (three months), take the following precautions to prevent potential HIV transmission to others:

- Abstain from sexual intercourse or use a latex condom with a water-based lubricant at all times during intercourse.
- Do not donate blood, plasma, organs, tissue or sperm.
- Do not share toothbrushes, razors, needles or other implements which may be contaminated with blood/body fluids.
- Do not become pregnant.
- Breastfeeding parents who experience a potentially significant exposure should be advised to discontinue breastfeeding while waiting for the source person's test results. If the source person is found to be HIV negative and it is determined that PEP is not necessary, breastfeeding can be resumed.

The risk of transmission to others is extremely small and the need for precautions should be discussed with a consultant familiar with HIV transmission.