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CENTRE *for* EXCELLENCE
in HIV/AIDS
EDUCATION & TRAINING

Module 2:

HIV Post-Exposure Prophylaxis (PEP)

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Faculty Disclosure

- **Faculty:** Dr. Marianne Harris

- **Relationships with commercial interests:**
  - **Grants/Research Support:** Amgen Canada Inc., Gilead Sciences Canada Inc.
  - **Speakers Bureau/Honoraria:** Gilead Sciences Canada Inc., Merck Canada Inc., ViiV Healthcare
  - **Consulting Fees:** Gilead Sciences Canada Inc., Merck Canada Inc., ViiV Healthcare
  - **Other:** none to disclose

- Antiretroviral medications are not approved by Health Canada as post-exposure prophylaxis (PEP) for the prevention of HIV. Recommendations for HIV PEP are considered "off-label" use of medications.

Disclosure of Commercial Support

- This program has not received any financial or in-kind commercial support.

- **Potential for conflicts of interest:**
  - No commercial organization has supported this program.

Mitigating Potential Bias

- All grants, research support, honoraria, and consulting fees are administered by the institution (BC-CfE and/or UBC).
- The content of the presentation is consistent with guidelines developed by the BC-CfE Post-Exposure Prophylaxis (PEP) Committee, a sub-committee of the Committee for Drug Evaluation and Therapy (CDET).
- Generic names of medications are used in place of brand names.

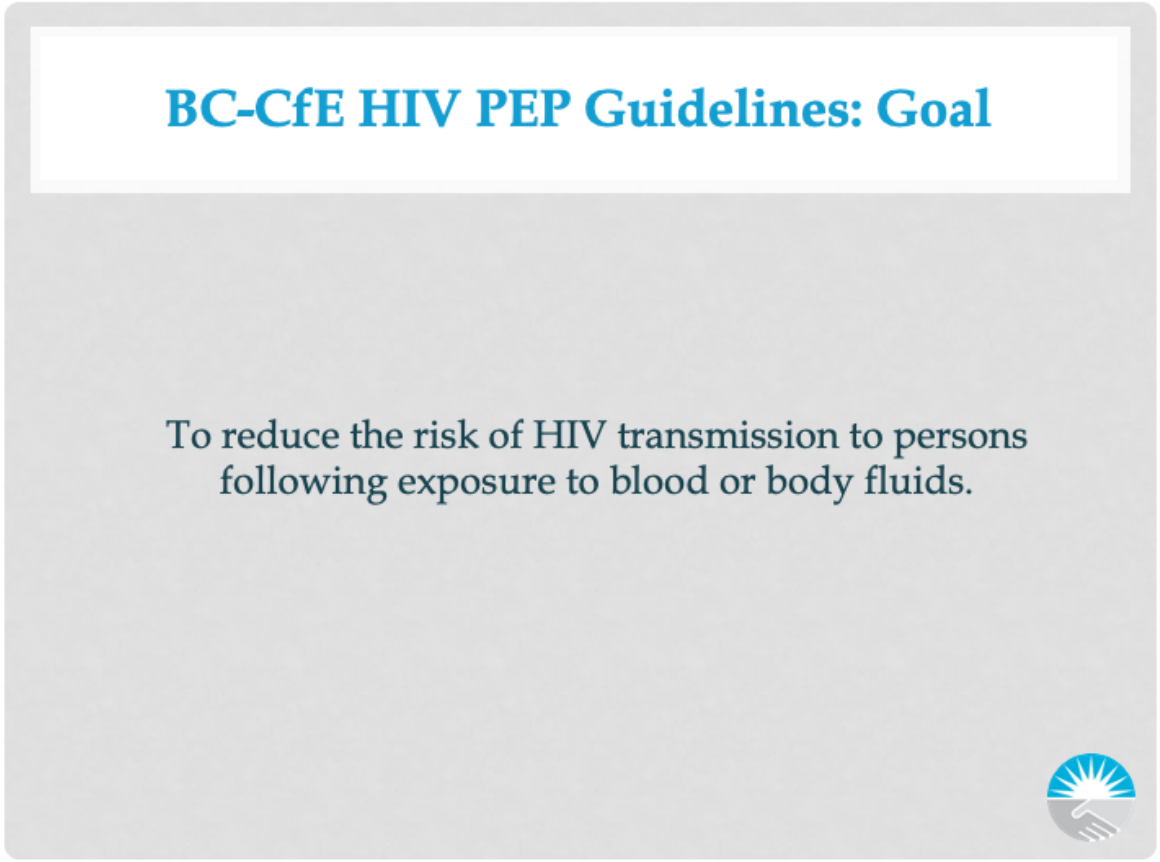
Learning Objectives

On completion of this module, participants will develop an understanding of:

- How to assess the risk of acquiring HIV infection from different types of exposures to blood and/or body fluids in the work place or community setting.
- When and how to prescribe PEP, and appropriate follow-up of patients after an exposure.

Outline

- **Goal of the BC-CfE Post-Exposure Prophylaxis (PEP) Program**
- **Definitions**
  - Potential exposure to HIV
  - Infectious and non-infectious body fluids
  - Infectious/ potentially infectious source person
- **Risk assessment**
  - Exposed person
  - Nature of exposure event
  - Source person(s)
- **Management recommendations**
  - Negligible risk of transmission
  - Significant risk of transmission
- **Follow-up recommendations**
- **Management of exposures in children**



The BC-CfE PEP guidelines (http://cfenet.ubc.ca/post-exposure-prophylaxis) are designed to deal specifically with exposures to Human Immunodeficiency Virus (HIV) and are not applicable to other exposures such as viral hepatitis. Health care providers caring for persons exposed to blood or body fluids should assess the risk of exposure to other pathogens including hepatitis B and hepatitis C viruses, and manage patients according to the recommendations of the BC Centre for Disease Control (http://www.bccdc.ca/resource-gallery/Documents/Guidelines%20and%20Forms/Guidelines%20and%20Manuals/Epid/CD%20Manual/Chapter%201%20-%20CDC/CPS_CDManual_BBFExpManage.pdf).

Sexual exposures may also result in the transmission of other sexually transmitted infections (STIs), e.g. viral hepatitis, syphilis, chlamydia, gonorrhea. Guidelines for the management 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/sexually-transmitted-infections). For other considerations in cases of sexual assault, refer to the BC Women's Sexual Assault Service (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).

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Definitions

Potential Exposure to HIV

An event where blood or other potentially infectious body fluid* from an infectious (or potentially infectious) source comes into contact with:

- **Subcutaneous tissue** – via percutaneous exposure
  - Hollow-bore needlestick injury
  - Cut or puncture with a sharp solid object
- **Mucous membranes**
  - Eye, mouth, nose
  - Vaginal, anorectal
- **Non-intact skin**
  - Wound less than 3 days old
  - Skin lesion causing disruption of the epidermis

*capable of transmitting HIV

Infectious Body Fluids*

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

*capable of transmitting HIV

Non-Infectious Body Fluids*

- Saliva
- Tears
- Sweat
- Nasal secretions
- Vomitus
- Sputum
- Urine
- Stool

*not implicated in the transmission of HIV unless visibly bloody

Infectious/Potentially Infectious Source Person

Source known to be HIV positive

- Risk is related to the viral load of the source
  - HIV transmission risk is lower if source is receiving antiretroviral therapy and has consistently undetectable viral load (<40 copies/mL) – risk from a single sexual exposure is zero in this setting
- Recommend PEP in an emergency situation in all cases of significant exposure
  - Request viral load in source if source is known and consents
  - Need for PEP continuation will be assessed by the BC-CfE physician on call for PEP

Source known to be at high risk of being HIV positive

- People who inject drugs (PWID)
- Men who have sex with men (MSM)
- Sexual partners of persons known to be HIV positive, or at high risk of being HIV positive

Unknown source

- Assess on a case-by-case basis
- PEP is not recommended for needlesticks from an abandoned needle

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. 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.

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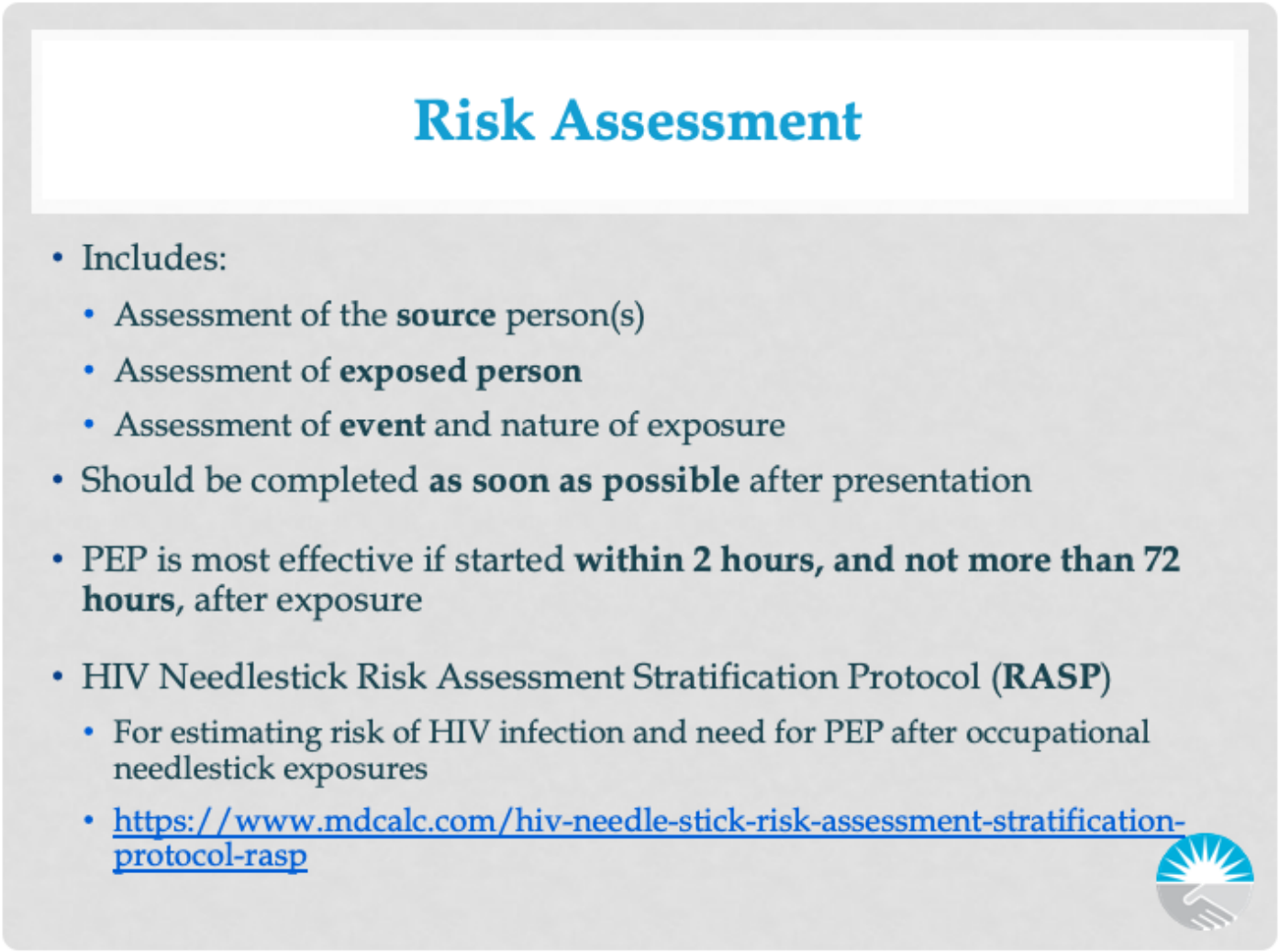
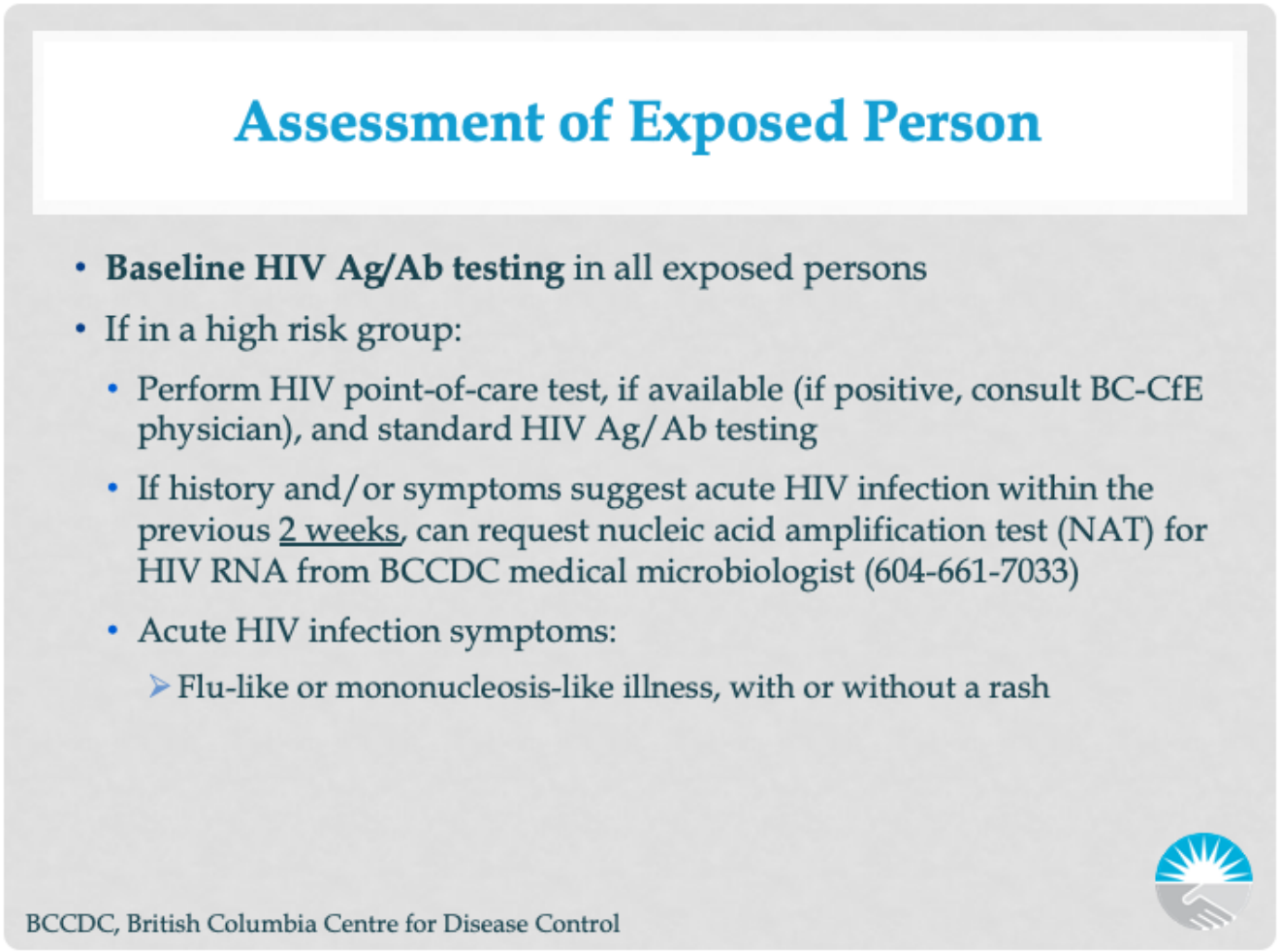
Risk Assessment



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 Stratification Protocol (RASP) is a useful tool for estimating the risk of HIV infection for occupational needlestick 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). 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.

Source:
Vertesi L. *CJEM* 2003; 5:46-48.



Perform **baseline HIV serology** (4th generation 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 he or she 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. 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 may be considered, 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.

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

Assessment of Exposed Person (cont.'d)

- Complete blood count (**CBC**) **and differential**, serum **creatinine**, and estimated glomerular filtration rate (**eGFR**)
- **Hepatitis B and C serology** (HBsAg, anti-HBc total, anti-HBs, anti-HCV)
- Assess for **other sexually transmitted infections (STIs),** if appropriate
- **Pregnancy test**, if appropriate
  - If exposed person is pregnant, contact the St. Paul's Hospital Ambulatory Pharmacy (1-888-511-6222)
  - PEP can be started with the existing kit
- If PEP is indicated, **do not withhold or delay starting PEP** pending results of lab tests

HBsAg, hepatitis B surface antigen;
Anti-HBc total, anti-hepatitis B core total antibody;
Anti-HBs, hepatitis B surface antibody;
Anti-HCV, anti-hepatitis C antibody

PEP should not be withheld pending lab results.
For assessment of other STIs (gonorrhea, chlamydia, syphilis), see http://www.bccdc.ca/health-professionals/clinical-resources/communicable-disease-control-manual/sexually-transmitted-infections

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.

Assessment of Event/Exposure Type

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 (large bore)
  - 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 an STI (especially genital ulcer disease) in either the source 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

Estimated Risk of HIV Transmission by Exposure Type from Known HIV Positive Source with Detectable Viral Load

Exposure	Estimated Risk (95% CI) per 10,000 acts	Estimated risk per act/event
Hollow bore needlestick injury[1]	23 (0-46)	0.23% or 1 in 435
Needle sharing – injection drug use	63 (41-92)	0.63% or 1 in 160
Occupational mucous membrane exposure[2]	9 (0.6-50)	0.09% or 1 in 1000
Penile-vaginal intercourse – risk to insertive partner	4 (1-14)	0.04% or 1 in 2500
Penile-vaginal intercourse – risk to receptive partner	8 (6-11)	0.08% or 1 in 1250
Anal intercourse (risk to insertive partner)	11 (4-28)	0.11% or 1 in 900
Anal intercourse (risk to receptive partner)	138 (102-186)	1.38% or 1 in 72
Oral intercourse (risk to either partner)	Low (0-4)	Low

1. Risk probably lower with cuts or punctures involving solid objects (vs. hollow bore needle)
2. Risk probably lower for exposures involving non-intact skin (vs. mucous membranes)

CI, confidence interval

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.
Transmission risk is increased by higher plasma viral load or acute or late-stage HIV infection in the source.
Transmission risk in sexual exposures is increased by genital ulcer disease, and decreased by condom use.
Overall, approximately 55% of people living with HIV in BC have a suppressed viral load on antiretroviral therapy (although there is variation in this proportion among different populations and locations in the province); therefore, for practical purposes, the above risk estimates could be halved.

Sources:

Ippolito G, et al. Arch Intern Med. 1993;153(12):1451-8.
Patel P, et al. AIDS. 2014;28(10):1509-19.
STOP HIV/AIDS, HIV Monitoring Quarterly Report for British Columbia, Fourth Quarter 2019. http://stophivaids.ca/qmr/2019-Q4/#/bc

Assessment of Source Person

The source's medical records cannot be accessed without his or her consent – if consent is given it should be documented.

HIV or viral load testing cannot be done on the source without his or her consent.

Three general scenarios:

1. Source known to be HIV positive
2. Source known but HIV status unknown
3. Source unknown

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 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+); and for the BC-CfE to share this information 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's medical records cannot be accessed in situations where the source has not provided verbal consent for such access, and/or the consent has not been documented.

Source Known to be HIV Positive

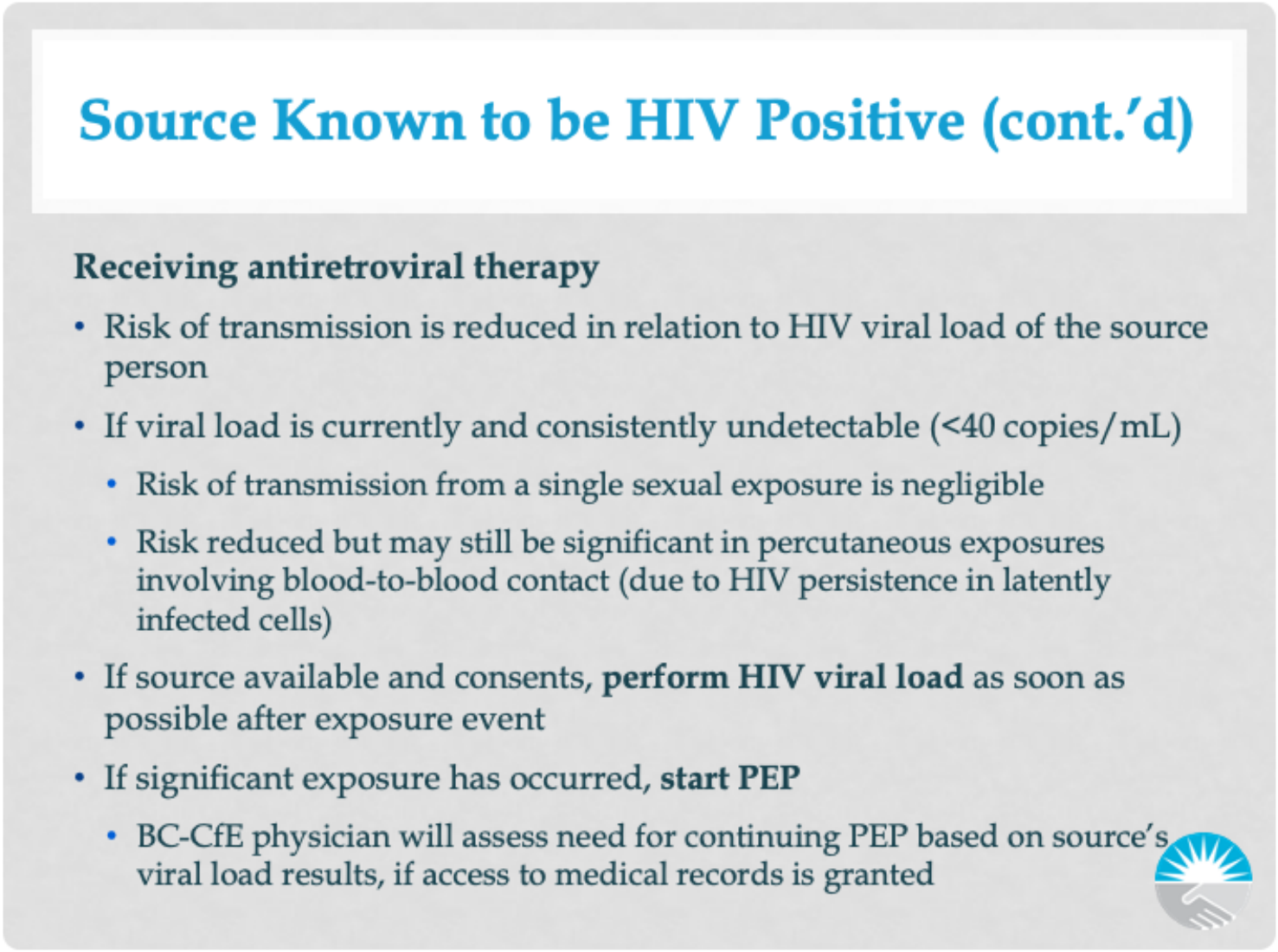
Not receiving antiretroviral therapy

- In general, significant exposures would warrant PEP

HIV positive source 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.



HIV positive source person receiving antiretroviral therapy

If the source's viral load is currently and consistently fully suppressed, the risk of transmission from a single sexual exposure is negligible. Undetectable viral load in the source may also reduce the risk of HIV transmission in percutaneous exposures involving blood-to-blood contact, 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).

If the source 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.

Role of Viral Load in Sexual Transmission

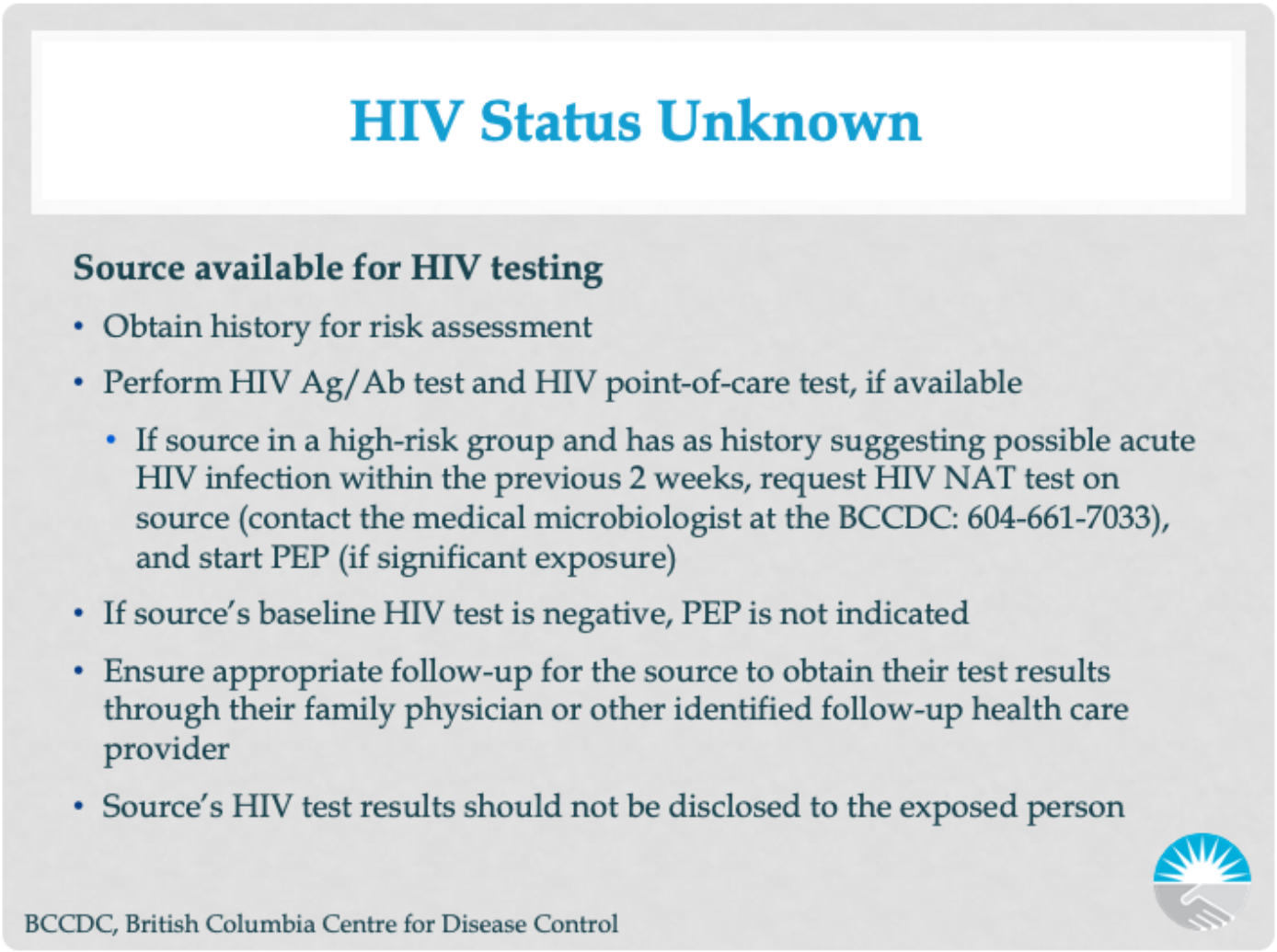
U=U HIV Undetectable = Untransmittable

"Scientists never like to use the word "Never" of a possible risk. But I think in this case we can say that the risk of transmission from an HIV-positive person who takes treatment and has an undetectable viral load may be so low as to be unmeasurable, and that's equivalent to saying they are uninfectious. It's an unusual situation when the overwhelming evidence base in science allows us to be confident that what we are saying is fact."

Anthony Fauci

Director, National Institute for Allergies and Infectious Diseases
United States National Institutes of Health

Source:
Eisinger RW, et al. JAMA. 2019;321(5):451-452.



Source 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 available and the source person agrees, an HIV point-of-care test can be performed at this time.

Investigation of whether a source patient might be in the window period is unnecessary for determining whether HIV PEP is indicated unless acute retroviral syndrome is clinically suspected. In circumstances where the source is known to be in a high risk group and has a history suggestive of acute HIV infection in the previous 2 weeks (i.e. a potential exposure and symptoms during that time) , an HIV NAT test should be requested, in conjunction with the standard HIV Ag/Ab assay, and prophylaxis should be started or continued (if exposure type warranted initiation) until both results are confirmed to be negative.

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

HIV Status Unknown (cont.'d)

Source not available for HIV testing, or unknown source

- Estimate risk of being HIV positive from community prevalence estimates for BC
- If source thought to be in a high-risk group, start PEP for significant exposures
- PEP is not recommended for needlesticks from a discarded needle
  - For special circumstances that could merit PEP, contact the St. Paul's Hospital Ambulatory Pharmacy (1-888-511-6222)

Source <u>not</u> available for HIV testing

When the source 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 (see next slide), and the type of exposure that has occurred. Those with an exposure type associated with increased HIV transmission (see slide 18: Estimated Risk of HIV Transmission), and source belonging to a high-risk group should be offered PEP.

Estimated Prevalence of HIV 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	Gender Unknown
Estimated probability of being HIV+	100%	13%	23%	0.009%	0.002%	0.006%

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

Sources:

Moore DM, et al. J Acquir Immune Defic Syndr. 2016;72(1):87-95.
Public Health Agency of Canada. https://www.canada.ca/en/public-health/services/hiv-aids/publications/i-track-enhanced-surveillance-hiv-hepatitis-associated-risk-behaviours-people-who-inject-drugs-canada-phase-2.html

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Management Recommendations

Negligible Risk of HIV Transmission

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)

OR

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

↓

PEP NOT recommended.

Consult with BC-CfE if an unusual exposure has occurred.

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

No PEP is recommended for negligible risk exposure.

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.

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, or
Mucous membrane or non-intact skin exposure, or
Sexual exposure (vagina or rectum)

AND

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

↓

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 BC-CfE 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).

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.

Refill Prescription for Significant Exposures

- The medications in the 5-day starter 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.
- 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 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.

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.

Follow-up Recommendations after Significant Exposures

If PEP is started

- CBC and differential, serum creatinine, eGFR: 2 and 4 weeks after exposure, **if any abnormalities identified on baseline testing**
- HIV Ag/Ab: 3 weeks, 6 weeks, and 3 months **after end of PEP**
- Anti-HCV Ab: 3 weeks and 3 months after exposure

If PEP is not started but was indicated

- HIV Ag/Ab: 3 weeks, 6 weeks, and 3 months after exposure
- Anti-HCV Ab: 3 weeks and 3 months after exposure

CBC, complete blood count; eGFR, estimated glomerular filtration rate
Ag/Ab, antigen/antibody; anti-HCV, hepatitis C antibody

Follow-up is required for persons having had a significant risk exposure to HIV, regardless of whether PEP is started.
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 washout period is estimated to be in the three-week range; hence, serologic testing should be delayed until after PEP completion.
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

Management of Exposures in Children

- Accidental needlesticks
  - Risk of HIV infection is negligible from discarded or abandoned needles
- Bites
  - Risk is negligible in bites from children
  - PEP should only be considered if the skin is broken and bleeding has occurred, and there is blood in the mouth of the biter who is known to be HIV positive
  - If a child bites an HIV-positive person, PEP may be considered if the skin is broken and there are areas of non-intact mucosa in the child's mouth
- Sexual assault
  - PEP may be considered
- Doses of meds in PEP starter kit can be modified according to child's weight
- Contact St. Paul's Hospital Ambulatory Pharmacy (1-888-511-6222) as soon as possible

The risk of children being infected with HIV from accidental needlestick injuries, biting, 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 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 BC-CfE PEP Guidelines, Table 2, page 18.

Summary

- **BC-CfE PEP Guidelines** are available at http://cfenet.ubc.ca/post-exposure-prophylaxis
- A **28-day course** of antiretrovirals is available for prevention of HIV infection following significant exposures to blood/body fluids in workplace or community settings
  - 5-day PEP starter kit: tenofovir DF, lamivudine, and raltegravir
  - 23-day refill prescription: emtricitabine-tenofovir DF and raltegravir
- **Risk assessment** includes assessing the source person(s), the exposed person, and the event
- PEP should be started **as soon as possible** after a significant exposure
- Baseline and follow-up **HIV testing** – final test at 3 months after the end of PEP (or after the exposure, if PEP indicated but not taken)
- **Questions:** contact St. Paul's Hospital Ambulatory Pharmacy (**1-888-511-6222**)
- Persons at risk of exposure to Hepatitis B, Hepatitis C, and/or STIs should be managed according to the recommendations of the BC for Disease Control (www.bccdc.ca)

STIs, sexually transmitted infections

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End of Module 2