

BCCDC Non-certified Practice Decision Support Tool: HIV Pre Exposure Prophylaxis (HIV PrEP)

Background

Effective January 1, 2018, eligible British Columbians have been able to access HIV pre-exposure prophylaxis (HIV PrEP) through the BC Centre for Excellence (BCCfE) Drug Treatment Program at no cost.

This decision support tool guides a registered nurse's (RN) assessment and management (i.e., testing and monitoring) of individuals eligible for, or currently taking, HIV PrEP and should be used alongside clinical judgement, current available evidence, individual competence and consultation with a healthcare team as required.

Scope

RNs act within autonomous scope of practice when providing assessment and on-going management for individuals taking HIV PrEP.

Completing a sexual health history and assessment, including the collection of specimens for sexually transmitted and blood-borne infection (STBBI) testing, falls within the scope of practice for all RNs who possess the competencies to do so. While the NNPBC Assessment and Diagnostic Guideline: STI DST is intended for use by RNs with Reproductive Health Certified Practice, it may serve as a useful guide for non-certified practice RNs to frame a comprehensive sexual health history.

RNs cannot prescribe HIV PrEP.

A client-specific order may be required for certain laboratory investigations outside an RN's scope of practice (e.g., eGFR, creatinine, CBC).

Organizational/employer policies and processes must be in place to allow RNs to work within this autonomous scope and to direct test results to the appropriate healthcare provider for follow up where appropriate.

RNs cannot diagnose or treat diseases, disorders or conditions that fall under <u>certified practice</u>.

Etiology

The human immunodeficiency virus (HIV) is a retrovirus that causes acquired immunodeficiency syndrome (AIDS) – the last stage of HIV disease.

HIV PrEP is the use of antiretroviral medication by HIV-negative individuals to reduce the risk of acquiring the infection caused by HIV.

Epidemiology

In Canada, recent estimates indicate that approximately 62,790 people were living with HIV at the end of 2020. The Public Health Agency of Canada (PHAC) estimates HIV prevalence in BC to be 9,637 people.

Over the past 10 years, the number of new cases of HIV in BC have steadily decreased over time, but this trend has changed recently.

For comparison, in the year 2022 in BC, there were 2.52 cases of HIV per 100,000 people, while in 2013 cases of HIV were 5.72 per 100,000.

Most recently however, the estimated rate for 2023 is expected to rise 3.41¹ per 100,000, a 35% increase from the previous year.

Efficacy of HIV PrEP

HIV PrEP is highly effective in the prevention of HIV when taken as prescribed.

In Canada, HIV PrEP is currently only available in pill form:

- Emtricitabine 200 mg/tenofovir DISPROXIL FUMARATE 300 mg (e.g. Truvada®)
- Emtricitabine 200 mg/tenofovir ALAFENAMIDE 25 mg (e.g. Descovy®)

Both have proven to be highly effective means of HIV prevention in randomized clinical trials, with reported efficacy in precenting HIV infection of over 90%.

¹ Data are preliminary and subject to change. The data were extracted on January 9, 2024.

Clinical Presentation

Sexual Health History and HIV PrEP Eligibility

During a comprehensive sexual health history and assessment, consider eligibility for HIV PrEP.

Referral for HIV PrEP initiation and/or further assessment is recommended with any of the following sexual health history findings:

- 1) For cis- and transgender men who have sex with men (MSM) and transgender women (TGW):
 - with a calculated HIV Incidence Risk Index for men who have sex with men (HIRI-MSM) score ≥10
 (Appendix A). A HIRI score can be completed based on previous, current or potential future sexual
 and drug use practices.
 - Reporting condomless anal sex and having any of the following:
 - infectious syphilis or rectal bacterial STI, particularly if diagnosed in the preceding 12months
 - o use of non-occupational post-exposure prophylaxis (nPEP) on more than one occasion
 - o ongoing sexual contact with a partner who is living HIV and who is not receiving stable antiretroviral therapy (ART) and/or does not have an HIV viral load <200copies/ml.
- 2) For persons who inject drugs (PWID), who report sharing injection equipment and:
 - who have an injecting partner who is living with HIV and who is not receiving stable ART and/or does not have an HIV viral load <200copies/ml.
- 3) For all other persons who do not fit into the above criteria who report condomless vaginal or anal sex and:
 - ongoing sexual contact with a partner who is living with HIV and who is not receiving stable ART and/or does not have an HIV viral loaf <200copies/ml.
- 4) Other populations clinically assessed to be at high risk for HIV infection including: unprotected vaginal/anal sex with partners from MSM/PWID population of unknown HIV status, transgender men, gender diverse individuals, people engaging in sex work².
- 5) Self-referral: self-referral for HIV PrEP may be an indication of undisclosed risk and merits further assessment.

² National data on HIV incidence among people engaging in sex work in scarce; as such, this eligibility criteria should be applied to these individuals based on these presence of other risk factors. *Tan et al. Canadian guideline on HIV pre-exposure prophylaxis and nonoccupational postexposure prophylaxis. 2017.*

Physical Assessment

Assess for symptoms of acute HIV infection/seroconversion illness (classic symptoms include: fever, malaise, myalgia, pharyngitis, rash, headache).

Diagnostic and Screening Tests

Baseline - Screening Tests

Careful consideration should be given to an individual's prior testing, immunization history, and exposure information when offering recommended baseline screening tests.

Table 1 outlines the required and recommended baseline screening tests for HIV PrEP initiation and enrollment as per the <u>BCCFE Guidance for the use of HIV PrEP</u>.

Table 1. Baseline Screening Tests

	Assay type			
Required Testing				
HIV Serology	4 th Generation Ab/Ag Assay*			
Hepatitis B Screen	hepatitis B surface antigen†			
Renal function	creatinine, eGFR‡			
Recommended Testing				
Gonorrhea Screen	urine NAAT test; throat, rectal and/or vaginal swabs dependent on type of sexual exposures reported			
Chlamydia Screen	urine NAAT test, throat, rectal and/or vaginal swabs dependent on type of sexual exposures reported			
Syphilis	T. pallidum EIA			
Hepatitis B Screen	hepatitis B surface antigen, core antibody, surface antibody			
Hepatitis C Screen	hepatitis C antibody if not known to be hepatitis C positive; hepatitis RNA if previously hepatitis C positive			
Renal function	urianalysis‡ or urine albumin to creatinine ratio (ACR) ‡			

	Assay type		
Additional Testing			
Pregnancy Test?	urine or serum HCG‡		
Complete Blood Count	cbc serology‡		

NB: All reactive HIV 4th generation Ab/Ag tests results will be reflexively tested at the BCCDC Provincial Public Health Laboratory (BCCDC PHL) with a confirmatory immunoblot assay. If syphilis EIA is reactive, rapid plasma regain (RPR) and T. Pallidum particle agglutination (TPPA) are done reflexively at the BCCDC PHL (a TPPA once positive, will not be repeated on any subsequent testing).

*If symptoms suggestive of acute HIV infection (recent contact risk coupled with the emergence of typical symptoms), and/or history of high-risk condomless sex within the previous 2 weeks, a nucleic acid amplification test (NAAT) for HIV RNA is recommended. Contact the BC Centre for Disease Control medical microbiologist on call at 604-661-7033 to discuss the option to order this test.

Documentation of a recent negative 4th generation HIV Ag/AB test (within the previous 15 days) MUST be provided on the enrollment form.

†Provide hepatitis B surface antigen (HBsAg) status. If client is HBsAg is positive, additional monitoring or consultation with a specialist is advised.

To assess for immunization status and eligibility, hepatitis B core and surface antibody screening is recommended.

‡Please note that for RN(C), a client specific order is required for these tests.

?Offer if indicated.

Management

Clinical Evaluation

PrEP Initiation

Refer to a nurse practitioner/physician (NP/MD) for initiation of HIV PrEP (e.g., completion of HIV PrEP enrolment and prescription request) and/or further assessment if required.

Perform medication reconciliation (list of all medications and supplements) to inform potential interactions or contraindications with HIV PrEP medication.

Follow up - Testing and Monitoring

While on HIV PrEP, follow-up is required at 1 month following initiation and every three months thereafter.

Table 2 outlines the testing and monitoring recommendations for follow up HIV PrEP appointments.

Table 2. Ongoing Testing and Monitoring

Recommended Testing	Assay Type	After 1 st month then every 3 months	Comments
HIV Serology	4 th Generation Ab/Ag Assay	x	Documentation to BCCfE is not required for ongoing HIV PrEP enrollment. Clinicians are responsible for monitoring ongoing HIV status.
Hepatitis C Screen	hepatitis C antibody if not known to be hepatitis C positive; hepatitis RNA if previously hepatitis C positive		Every 6 months based on risk
Gonorrhea Screen	urine NAAT test; throat, rectal and/or vaginal NAAT swabs	х	Screen as per exposure risks
Chlamydia Screen	urine NAAT test; throat, rectal and/or vaginal NAAT swabs	х	Screen as per exposure risks
Syphilis Screen	Syphilis Enzyme Immune Assay (EIA)	х	Screen as per exposure risks
Renal Function	creatinine, eGFR	X	Documentation to BCCfE is not required for ongoing HIV PrEP enrollment. Clinicians are responsible for monitoring ongoing renal function. A urinalysis or urine albumin to creatinine ratio (ACR) may be ordered as part of ongoing management

Recommended Testing	Assay Type	After 1 st month then every 3 months	Comments
Pregnancy Test	urine or serum HCG	х	As indicated

On-going Management

The following are components of ongoing management of HIV PrEP:

- Assess for signs and symptoms of acute HIV infections/seroconversion illness. Contact the BCCDC medical microbiologist on call at 604-661-7033 to inquire about the option to order a NAAT test in these instances.
- Assess for <u>PEP</u> if recent high risk exposure and more than 3 doses have been missed in the period
 of a week.
- Review of screening and diagnostic tests
 - o Ensure all recommended tests based on exposure risk have been completed.
 - Tests necessitating a client specific order require sign off by a NP/MD. Refer to your organizational/employer policies and processes.
 - Verify results are within normal range; results falling outside of a normal range (e.g. renal function) require consultation with NP/MD.
- Ensure treatment is completed for all positive STIs.
- Review medication history/changes to medication.
- Assess medication adherence.
- Assess medication side effects (common = headache, GI upset, nausea, flatulence, abdominal pain, decreased weight – typically resolve in a few weeks of starting HIV PrEP).
- Assess on-going exposures and need for continued use of HIV PrEP.
- Additional assessment as appropriate (e.g., social and environmental factors)/
- Ensure lab requisitions for testing at follow up appointment(s) are provided.

Consultation or Referral

- HIV positive result or suspected acute HIV infection.
- Hepatitis B virus (HBV) infection individuals with chronic HBV infection require a referral to a
 physician with HBV treatment experience.
- Abnormal renal function results (unless reviewed by NP/MD and HIV PrEP continuation approved).
- Known osteoporosis or osteopenia.

BCCDC | HIV PrEP

- Severe or unexpected side effects.
- Expected side effected (e.g., nausea, diarrhea) persisting longer than 1 month.
- Medication/supplement additions or changes that may interact with or have overlapping toxicities with HIV PrEP use (e.g., NSAIDS) or that may falsely elevate serum creatinine and lower eGFR (e.g., creatinine supplements).

HIV PrEP Dosing

In Canada, HIV PrEP is currently only available in pill form as either:

- Emtricitabine 200 mg /tenofovir DISPROXIL FUMARATE 300 mg (e.g., Truvada®)
- Emtricitabine 200 mg /tenofovir ALAFENAMIDE 25 mg (e.g., Descovy®)

DAILY

As daily oral therapy, HIV PrEP is prescribed as one tablet Emtricitabine 200 mg /tenofovir

DISPROXIL FUMARATE 300 mg (e.g., Truvada®) OR Emtricitabine 200 mg /tenofovir

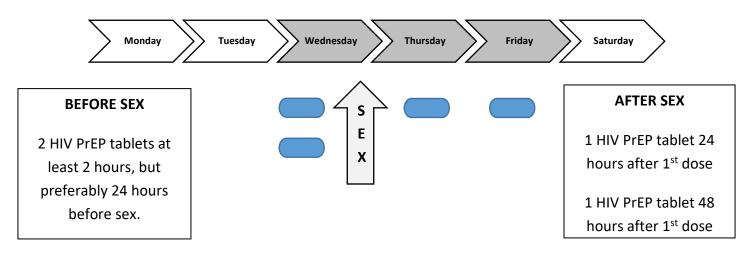
ALAFENAMIDE 25 mg (e.g., Descovy®) to be taken once per day

ON-DEMAND

For MSM without hepatitis B (HBV) infection for whom on-demand dosing is appropriate, HIV PrEP is prescribed as two tablets of Emtricitabine 200 mg /tenofovir DISPROXIL FUMARATE 300 mg (e.g., Truvada®), 2 to 24 hours prior to anal sex, followed by one tablet daily until 48 hours after the last episode of anal sex.

- 2 pills in the 2 24 hours before sex (closer to 24 hours preferred)
- 1 pill 24 hours after the initial two-pill dose
- 1 pill 48 hours after the initial two-pill dose

2-1-1



NB: Descovy® has NOT been approved for on-demand use.

Partner Notification

Not applicable for HIV PrEP.

Potential Complications

HIV PrEP oral therapy is well tolerated.

About 10% of people who start HIV PrEP will have some short-term, mild side-effects.

Side-effects may include:

- gastrointestinal symptoms (diarrhea, nausea, decreased appetite, abdominal cramping or flatulence).
- dizziness or headaches

Side-effects are usually mild and resolve without stopping HIV PrEP.

Typically, these symptoms start in the first few days or weeks of HIV PrEP use, last a few days and almost always resolve within a month.

Renal

A small percentage of individuals will not be able to take HIV PrEP because of kidney problems.

Renal function tests (creatine and urinalysis or urine albumin-to-creatinine ratio) should be done prior to starting individuals on HIV PrEP and for continued monitoring while on HIV PrEP.

BCCDC | HIV PrEP

Bone mineral density

A slight decrease in bone mineral density (BMD) has been observed in people take TDF-containing medications.

BMD typically returns to normal once HIV PrEP is stopped.

Studies have not demonstrated an increase in bone fractures as a result of these observed decreases in BMD.

Additional Education

Refer to the BCCDC HIV PrEP Clinician and Client Resources on <u>Smart Sex Resource</u> for detailed information on HIV PrEP effectiveness, safety, starting, taking and stopping HIV PrEP.

Refer to the <u>BC Centre for Excellence in HIV/AIDS Guidance for the Use of Pre-Exposure Prophylaxis (PrEP) for the Prevention of HIV Acquisition in BC</u> for additional detailed information and guidance when assessing for and managing individuals taking HIV PrEP.

Offer reminders and support in completing follow-up testing as per organizational/employer policies and processes, prior to any subsequent appointment.

Appendix A: HIRI-MSM Risk Calculator

HIRI-N	HIRI-MSM Risk Index Calculator (Score ≥ 10 Suggests HIV Incidence of 2% in Vancouver)						
	Question	Response	Score				
1	How old are you today?	If <18 years, score 0 If 18-28 years, score 8 If 29-40 years, score 5 If 41-48 years, score 2 If 49 years or more, score 0					
2	In the last 6 months, how many men have you had sex with?	If >10 male partners, score 7 If 6-10 male partners, score 4 If 0-5 male partners, score 0					
3	In the last 6 months, how many times did you have receptive anal sex (you were the bottom) with a man without a condom?	If 1 or more times, score 10 If 0 times, score 0					
4	In the last 6 months, how many of your male sex partners were HIV-positive?	If >1 positive partners, score 8 If 1 positive partner, score 4 If 0 positive partner, score 0					
5	In the last 6 months, how many times did you have insertive anal sex (you were the top) without a condom with a man who was HIV-positive?	If 5 or more times, score 6 If 0 times, score 0					
6	In the last 6 months, have you used methamphetamines such as crystal or speed?	If yes, score 6 If no, score 0					
	Add down entries in right to calculate total score:		Total Score				

References

- Alberta Health Services Alberta STBBI OSAP PEP/PrEP Working Group. Alberta HIV pre-exposure prophylaxis (PrEP) guidelines. February 2021. Available: https://www.albertahealthservices.ca/assets/info/hp/srh/if-hp-srh-hiv-prep-guidelines.pdf
- British Columbia Centre for Disease Control. HIV/AIDS reports. Available: http://www.bccdc.ca/health-professionals/data-reports/hiv-aids-reports
- British Columbia Centre for Excellence in HIV/AIDS. Guidance for the use of pre-exposure prophylaxis (PrEP) for the prevention of HIV acquisition in British Columbia. Updated June 2020. Available:

 https://www.bccfe.ca/sites/default/files/uploads/publications/centredocs/prep_guidelines_17-jun-2020.pdf
- Canadian Institutes of Health Research. CIHR HIV/AIDS and STBBI research initiative. Strategic plan 2022-2027. 2022. Available: https://cihr-irsc.gc.ca/e/documents/hiv_strat_plan_2022-27_en.pdf
- <u>Gilead Sciences. Product Monograph Descovy. January 2022. Available: https://www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy_pi.pdf</u>
- <u>Gilead Sciences. Product Monograph Truvada. October 2023. Available:</u>
 https://www.gilead.com/~/media/files/pdfs/medicines/hiv/truvada/truvada_pi.pdf
- Jourdain H, Billioti de Gage S, Desplas D, Dray-Spira R. Real-world effectiveness of pre-exposure prophylaxis in men at high risk of HIV infection in France: a nested case-control study. Lancet Public Health. June 2022. Vol 7: e529-36.
- O Murchu E, Marshall L, Teljeur C, et al. Oral preexposure prophylaxis (PrEP) to prevent HIV: a systematic review and meta-analysis of clinical effectiveness, safety, adherence and risk compensation in all populations. BMJ Open 2022;12:e048478. doi:10.1136/bmjopen-2020-048478
- Pico-Espinosa OJ, Hull M, MacPherson P, Grace D, Lachowsky N, Gaspar M, Mohammed S, et al. Reasons for not using pre-exposure prophylaxis for HIV and strategies that may facilitate uptake in Ontario and British Columbia among gay, bisexual and other men who have sex with men: a cross-sectional survey. June 27, 2023 11 (3) E560-E568; DOI: https://doi.org/10.9778/cmajo.20220113
- Public Health Agency of Canada. Estimates of HIV incidence, prevalence and Canada's progress on meeting the 90-90-90 HIV targets, 2020. July 2022. Available: https://www.canada.ca/content/dam/phac-aspc/documents/services/publications/diseases-conditions/estimates-hiv-incidence-prevalence-canada-meeting-90-90-90-targets-2020.pdf

- Public Health Agency of Canada. HIV in Canada: 2021 surveillance highlights. May 2023. Available: https://www.canada.ca/content/dam/phac-aspc/documents/services/publications/diseases-conditions/hiv-2021-surveillance-highlights/PHAC-HIVinCanada2021-Info-EN-2023Update_V5.pdf
- Tan, D. H. S., Hull, M. W., Yoong, D., Tremblay, C., O'Byrne, P., Thomas, R., et al.: Biomedical HIV Prevention Working Group of the CIHR Canadian HIV Trials Network. (2017). Canadian guideline on HIV pre-exposure prophylaxis and nonoccupational postexposure prophylaxis. CMAJ: Canadian Medical Association Journal 189(47), E1448-E1458. doi:10.1503/cmaj.170494 Updated version June 2018.
- US Public Health Service. Preexposure prophylaxis for the prevention of HIV infection in the United States 2021 update. A clinical practice guideline. Available: https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf