

PrEP for 2SGBTQ men: Everything you need to know about PrEP



Photo credit: Tele-PrEP Fenway

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- What is PrEP?
- How PrEP works to prevent HIV infection?
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- Stigma of PrEP use
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- References & resources



Learning Objectives

- Describe what is PrEP & how it works
- Demonstrate knowledge of HIV prevention, treatment and care
- Practice a health promotion and client centered approach
- Produce competencies in cultural humility, cultural safety, and clinical care

What is PrEP?



- PrEP is anti-HIV medication to prevent HIV-infection
- PrEP stands for Pre-Exposure Prophylaxis.
 - Not the same as PEP
 - PEP(post- exposure prophylaxis) taken within 72 hours of HIV exposure
- PrEP does not prevent STIs.
- PrEP is made of two anti-HIV drugs: Emtricitabine(FTC)+ Tenofovir (TDF)
- Approved by Health Canada in 2016

The drugs in PrEP are emtricitabine and tenofovir. "Emtricitabine is called a nucleoside reverse transcriptase inhibitor, while tenofovir is called a nucleotide reverse transcriptase inhibitor." Both drugs are known as anti-HIV medications called nucleotide reverse transcriptase inhibitor (NRTIs).

Canadian guidelines on HIV PrEP (2017, 2018)



- Gay, bi and other men who have sex with men
- Heterosexual exposure, including women reporting condomless intercourse with partners of confirmed or unconfirmed transmissible HIV status (CMAJ, 2022)
- People who inject drugs and share injection equipment (CMAJ, 2022)
- Regimens recommended:
 - tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) 300/200 mg once daily (*strong recommendation*; high quality of evidence).
 - alternative, TDF/FTC 300/200 mg administered "on demand" (two pills taken together 2 to 24 hours before first sexual exposure, followed by one pill daily until 48 hours after last sexual activity) may be considered in MSM

CMAJ 2017 November 27;189:E1448-58. doi: 10.1503/cmaj.170494



Tenofovir Disoproxil Fumarate (TDF) vs. Tenofovir Alafenamide (TAF)

- 2 types of tenofovir
 - Tenofovir Disoproxil (TDF) & Emtricibine is 300mg/200 mg
 - Tenofovir alafenamide (TAF) & Emtricibine is 25mg/200mg (a prodrug)
- What is a prodrug?
 - A prodrug is a formulation of a drug, is metabolized (i.e., converted within the body) into a pharmacologically active drug.
- TAF is a prodrug of tenofovir, the same active ingredient in tenofovir disoproxil fumarate (TDF) currently used for PrEP
- TAF(prodrug) is absorbed more quickly than <u>TDF</u>
 - produces higher levels of the active drug- tenofovir diphosphate, in cells
 - can be given in smaller doses
 - leading to lower drug levels in the blood
 less exposure for the kidneys, bones and other organs.

TDF, TAF, brand, trade and generic name & SFX SEXUAL HEALTH ALLIANCE

Brand name: Truvada

Trade name: Tenofovir

- Generic name is: emtricitabine (FTC) and tenofovir disoproxil fumarate (TDF)
- Dose: 200mg/300mg
- Tenofovir alafenamide (TAF), "a new formulation that has lower concentrations in the blood but reaches higher levels in cells, is as effective as the older version, tenofovir disoproxil fumarate (TDF)"
 - Higher levels in cells as in intracellular levels
- TAF (Vemlidy) is indicated for the treatment of chronic HBV with compensated liver disease

- Switching from TAF to TDF the older resulted in modest weight loss in people with HIV in the Swiss HIV Cohort.
- Switching from TAF to TDF also brought benefits in the forms of reduced cholesterol and triglycerides.
- In contrast, switching from TAF-containing treatment to a two-drug combination of dolutegravir/lamivudine or injectable cabotegravir/rilpivirine did not lead to any changes in weight.
- * SFX, side effects



- Descovy (FTC+TAF) is a formulation of Tenofovir by Gilead (no generic)
- Truvada is FTC+ TDF (drug patent has expired for Gilead)
- Generic is FTC+TDF
- All three forms of the drugs are <u>99% effective</u> against HIV-infection





Photo credit: The Rainbow Times



Photo credit: The Village Pharmacy

Switching from TAF to TDF, and vice versa sexual Health

- Switching from tenofovir alafenamide (TAF) to the older formulation of tenofovir disoproxil (TDF)
 resulted in modest weight loss in people with HIV in the Swiss HIV Cohort, researchers report in
 the journal Clinical Infectious Diseases.
- Switching from TAF to TDF also brought benefits in the forms of reduced cholesterol and triglycerides, improved lipid profile.
- In contrast, switching from TAF-containing treatment to a two-drug combination of dolutegravir/lamivudine or injectable cabotegravir/rilpivirine did not lead to any changes in weight.

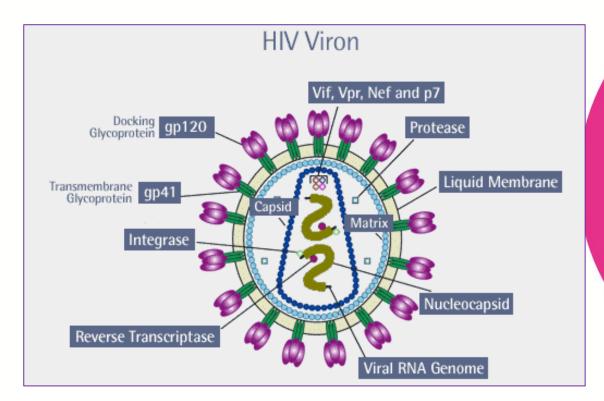
Kauppinen, K. J et al. (2022). Switching from tenofovir alafenamide to tenofovir disoproxil fumarate improves lipid profile and protects from weight gain. DOI: 10.1097/QAD.000000000000003245
https://pubmed.ncbi.nlm.nih.gov/35727143/



Question 1

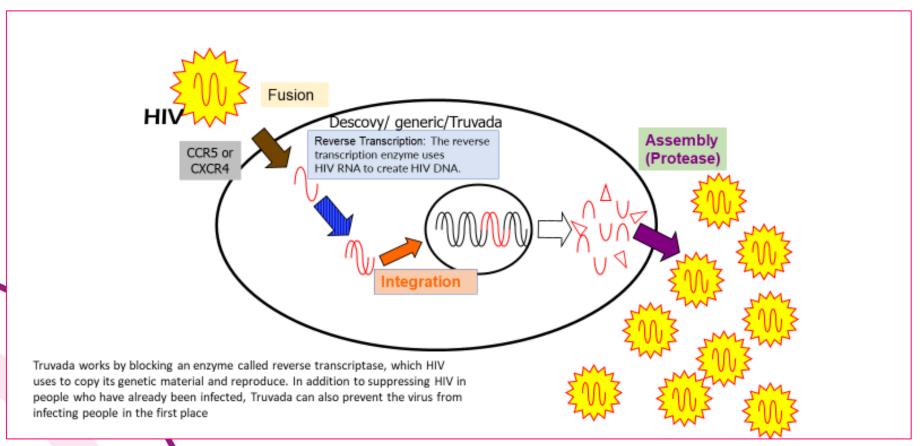
- HIV replicates in the cell using different enzymes. Which enzyme in the cell does
 TDF or TAF prevent HIV replication?
- a). Fusion of cell/co-receptors
- b). Reverse transcriptase
- c). Integrase
- d). Protease

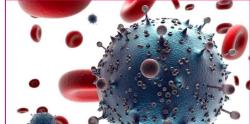
Answer in **pdf** document





How does tenofovir prevent HIV infection in the cell?











2.3 mins https://www.youtube.com/watch?v=jyDHRJ_zwQ4



Intracellular levels of TDF & TAF

- TAF was developed –due the slow metabolism of TDF meant that high levels of TDF persisted extracellularly in the blood
 - Side effects of kidney dysfunction and bone demineralization were attributed to TDF
- TAF produced lower plasma levels of tenofovir than TDF, but intracellular levels were fourfold higher with TAF.
- The intracellular concentration of tenofovir disphosphate reached when TAF was taken once every 3 days.
 - It was 2.6 times higher inside peripheral blood mononuclear cells (PBMCs) than when TDF/ daily.

NAM. (2021): One dose of TAF every three days



Question 2

Most of the anti-HIV medications are metabolized by the liver. Tenofovir is the only anti-HIV medication metabolized by the...

- a) Heart
- b) Kidneys
- c) Gastrointestinal tract

Answer in **pdf** document



PrEP & kidney function

- Tenofovir is excreted/eliminated from the body by the kidney in the urine
- TDF can damage the tiny structure known as proximal tubules in the kidney
 - Impaired kidney function can cause slower clearance of creatinine, a by-product of muscle metabolism
 - Increase in creatinine, decrease in eGFR <60, low phosphates, protein in urine
 - For GBMSM who take protein and creatine supplements, to re-evalute creatinine
 - PrEP (TDF) not for clients with eGFR < 60 umol/L or ml/min/1.73 m2
 - TAF for clients with eGFR 30-60
- TDF as a cause of acute kidney injury (AKI) or chronic kidney disease (CKD) is uncommon, and clinicians should actively exclude other causes of renal disease
- The use of tenofovir for PrEP can be limited by the nephrotoxicity



Question 4

The functions of the kidney are the following: Kidneys filter the blood and help remove wastes and extra fluid from the body. The kidneys also help control the body's chemical balance. The kidneys are part of the urinary system, which includes the ureters, bladder, and urethra.

- a) True
- b) False



Photo credit: julien-tromeur-tl3C_nZzHOo-unsplash

How is tenofovir metabolized in the body? SEXUAL HEALTH ALLIANCE

- Tenofovir is processed by the kidneys
- Many other HIV drugs are used/processed/metabolized by the liver, except tenofovir
 - Tenofovir is excreted through the "glomerular filtration and active tubular secretion"
 - Tenofovir can cause harm on the kidney tubules
 - The tubules reabsorb calcium (for bone health)
- What is the kidney tubules?
 - "One of millions of tiny tubes in the kidneys that returns nutrients, fluids, and other substances that have been filtered from the blood, but the body needs, back to the blood. The remaining fluid and waste in the renal tubules become urine."

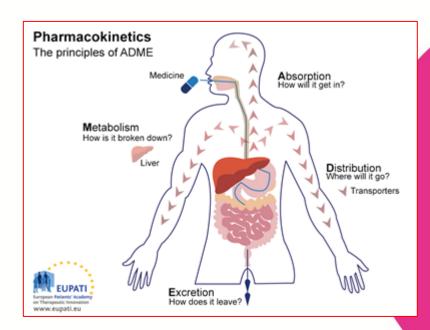
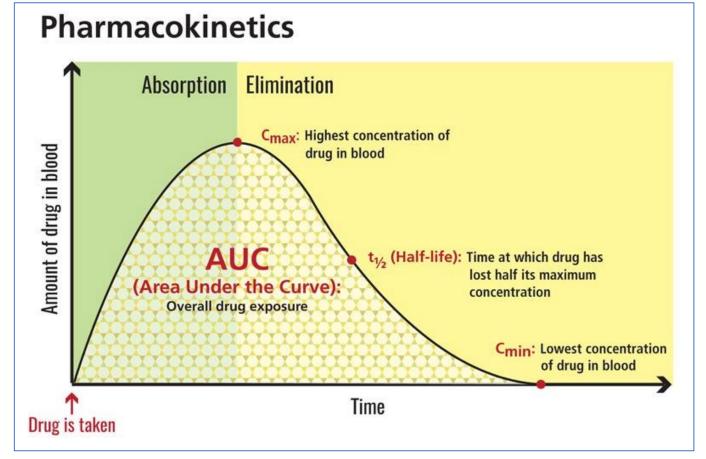


Photo Credit: Genomind



Absorption, elimination, distribution, metabolism, and excretion

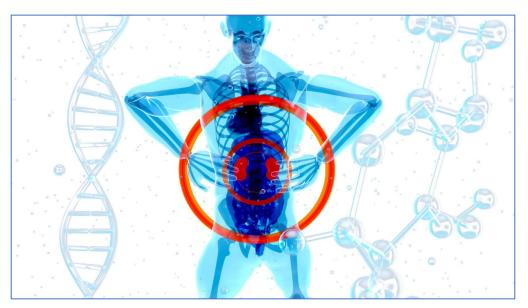


A snapshot of drug absorption, elimination in the blood.



Question 3

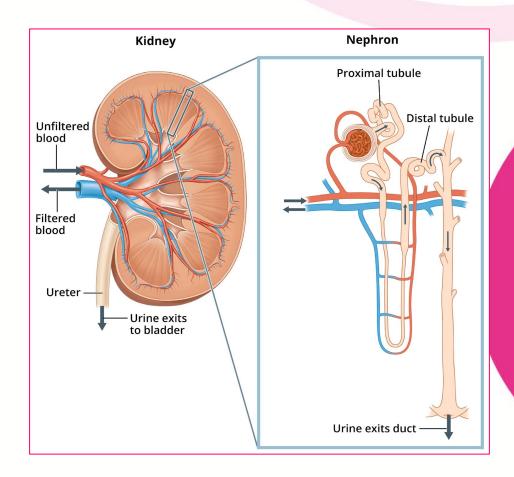
- 1. Kidney function begins to decline at age 40 and declines at a rate of about 1% per year beyond age forty. Rates may differ in different individuals.
- True OR False
- 2. eGFR is a test to measure of how efficient your kidneys are functioning.
- True OR False





Side effects of tenofovir

- The common side effects of tenofovir are include, diarrhea, nausea, fatigue and headache
- Can affect kidney and bone health
- Bone density (>95% of filtered calcium reabsorbed along renal tubules)
- Lactic acidosis: increase in lactic acid (e.g., renal tubular acidosis)



Side effects & contraindications of Tenofovir

- PrEP daily or on demand 2-1-1: kidney toxicity is rare (NATAP, 2021)
- Prenevir study, 2017-2020: (n= 499 TDF/FTC daily; n=494 TDF/FTC on demand, n=260 switched study arms)
 - Conclusion: serious kidney AE proved rare with all 3 PrEP methods-daily, on-demand, and switching.
- TAF offers benefits for those with reduced kidney function: TAF in Descovy does not have the same beneficial effect on blood lipids, and it may be linked to greater weight gain. Or referred to as return to health for some PLHIV.

OPERA study: PLHIV on TDF regimen (of ARV combination with boosting ritonavir or cobicistat risk of developing kidney diseases)

 TDF leads to lower cholesterol and triglyceride levels, which can lessen cardiovascular risk

Contraindications:

- for persons with low phosphate in the blood.
- increased blood acidity (high levels of lactic acid)
- Fanconi syndrome, (kidneys do not absorb electrolytes & other substances resulting in excessive urination, thirst and vomiting)



Tenofovir in antiretrovirals for PLHIV

STRIBILD	GENVOYA	Biktarvy
elvitegravir, cobicistat, emtricitabine, and tenofovir disoproxil fumarate (300 mg)	elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide (25 mg)	Bictegravir, emtricitabine, and tenofovir alafenamide (25 mg)
tablets, for oral use	tablets, for oral use	tablets, for oral use



PrEP for Hepatitis B virus

- Persons with chronic <u>hepatitis B</u> who are at risk of contracting HIV can receive a
 double benefit from oral <u>PrEP</u> tenofovir-based formulations that protect from
 HIV and reduce hepatitis B virus (HPV) load.
- A recent review weighs the evidence for offering oral PrEP to this population and finds best practices to favor benefit against risk.
- People with chronic HBV who stop PrEP should be closely monitored for HBV reactivation and hepatitis flares after antiviral cessation.

PrEP Protection Against HIV is Complicated by Chronic HBV (contagionlive.com)

What is eGFR?



- Glomerular Filtration Rate (GFR) is the amount of blood filtered every minute by tiny filters in the kidneys called glomeruli. It measures how efficient your kidneys are functioning.
- Kidneys remove waste and excess water from the blood.
 If the kidneys are not working well, this affects the filtration rate and it could be kidney damage.
- As per Canadian PrEP guideline, eGFR should be >60 mL/min for use of PrEP
- GFR is affected by many factors, such as: time of day, dietary protein intake, exercise, age, pregnancy, obesity, high blood sugar, antihypertensive drugs (to <HBP), acute and chronic kidney disease

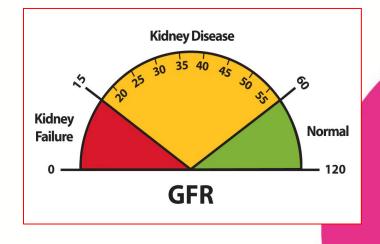
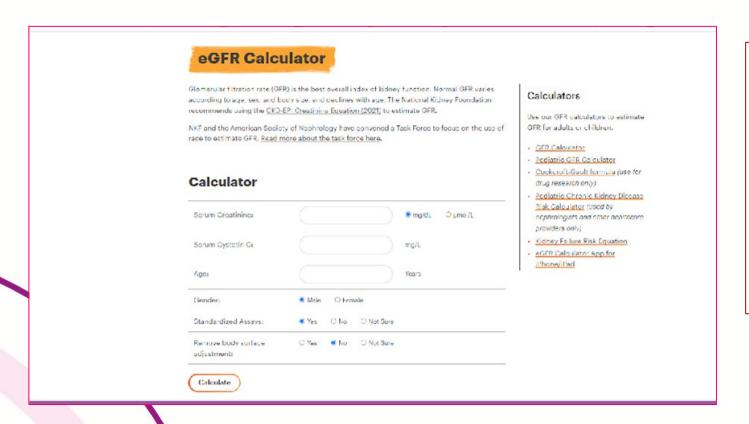


Photo credit: National Institute of Diabetes and Digestive and Kidney Diseases.



Kidney function: Glomerular filtration rate

Glomerular filtration rate is considered the best measure of kidney <u>function</u>



"People with preexisting kidney problems, including an eGFR below 60, should not take Viread, Truvada or other coformulations containing TDF." POZ 2021

Re: https://www.kidney.org/professionals/kdoqi/gfr_calculator



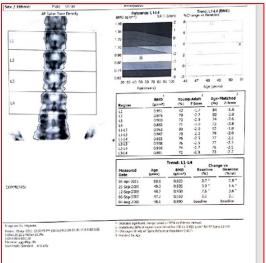
Race correction in estimates of kidney function

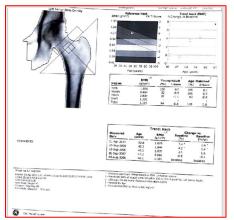
- A report in CMAJ 2021 discussed the calculation of eGRF for Black patients. Calculations of eGFR for Black persons, "can falsely increase eGFR up to 10 %, which can lead to delayed diagnosis and poorer outcomes"
- Important reminder for ACB communities on tenofovir based ARV or PrEP and discuss eGFR, kidney function, and bone health
- In the lab report it has "For patients of African descent, the reported eGFR must be multiplied by 1.15." This was reviewed in 2020, Flawed Racial Assumptions in eGFR Have Care Implications in CKD and a task force set up to focus on the use of race to estimate GFR.
- In 2020, the National Kidney Foundation (NKF) and the American Society of Nephrology (ASN) convened a Task Force to recommend an evidence-based race-free approach to estimated glomerular filtration rate (eGFR). In 2024 the NKF/ASN Task Force published the final report. It is available here-based race-free approach to estimated glomerular filtration rate

Bone health

- Bone mineral density (BMD) is measured by DXA scan of the hip and spine.
- Changes in BMD and bone biomarkers after starting TDF are small—around 1% to 3%
- Improvement in bone health when switched from TDF to TAF
- Bone Density Scan or Bone Mineral Scan is to measure bone loss, osteopenia, and osteoporosis.
- As per Canadian PrEP guideline for bone health:
 - DXA is not advised unless otherwise indicated according to Osteoporosis Canada guidelines at baseline or during PrEP use.
 - PrEP may be considered in people with low bone mass or osteoporosis after the risks and benefits have been discussed with them.







Example of bone density test results.



PrEP and bone density

• A small proportion of people experienced bone loss after starting daily (TDF/FTC; *Truvada* or generic equivalents) for PrEP, and those who were more adherent saw a greater effect.

N= 7,698 adults on FTC/TDF for 8 yrs Age 18-29 & 30-39 yrs	40% good adherence	60 % had suboptimal adherence <90%	No history of osteoporosis(substantial bone loss; Tscore of -1 or less)	No history of osteopenia (mild bne loss (tscore of -1 or less)	Follow up pf 502 days
30% white, 40% Latino, 10 Asian, 7% Black			DEXA scan	DEXA scan	
217 participants			3% developed osteoporosis	3% developed osteopenia	

- Recommendations: counseling on the incidence of osteoporosis and osteopenia as well as routine screening should be considered for people starting daily TDF/FTC for PrEP., a baseline bone density scan and later every two year.
- Explore benefits of PrEP taken before and after sex- on-demand PrEP or the 2+1+1 schedule



PrEP 2-1-1

PrEP 2-1-1	What, when to take, how to take, when not to take PrEP
Dosage	On demand PrEP 2-1-1 2 pills are taken 2 to 24 hours before sex, 1 pill 24 hours after the initial dose, and one final dose 24 hours later
Not recommended /do not take:	Descovy as it is TAF (25mg/200mg) vs. TDF (300mg/200 mg
2-1-1 is effective for:	people who have receptive/bottom during anal sex people who have insertive /top during anal sex people who insertive/ top during front hole or vaginal sex
Not effective for	people who have receptive/bottom during front hole or vaginal sex

Re: SFAF. (2018). For people having anal sex, PrEP 2-1-1 is effective at preventing HIV

PrEP for trans-feminine & trans-masculine persons



- Access to transitional related surgery (TRS, GAS, SRS), HRT improves uptake of PrEP
- PrEP does not affect feminizing HRT or drug concentration of HRT
- In HTPN083 study found long acting cabotegravir was highly effective in reducing HIV infection, and use of HRT did not affect cabotegravir levels in blood (CATIE, 2024)
- PrEP drugs does not increase or decrease levels of HRT
- HRT taken by trans women appear to slightly lower levels of the PrEP drug tenofovir, but not enough to affect the efficacy of PrEP daily
- Hormones taken by trans men do not appear to raise or lower levels of PrEP
- Event-based dosing, on demand PrEP/ 2-1-1 is not recommended for either trans women or men.



<u>PrEP for cis and trans women</u>. 2024. Prevention in Focus. CATIE.

NAM. aidsmap (2021). Interactions between PrEP and gender-affirming hormone therapy



- A few updates to PrEP guidelies in UK as of 2024.
- UK guidelines include additional recommendations that could make PrEP even easier. This includes that people who currently need 6-7 daily doses a week might only need 4 or more.
- Event-based dosing can also now be used by everyone. This uses either 2:1:1 or 2:7 dosing (2 pills before sex and continue for 7 days).
- The guidelines cover starting and stopping PrEP and new versions of PrEP (TAF/FTC and injectables).
- The changes are based on recent studies that update our understanding of how PrEP works. Instead of needing to have good drug levels in vaginal or anal tissue, PrEP efficacy is now explained by drug levels in cells called peripheral blood mononuclear cells. (PBMC). More on PBMC here
- Because drug levels in PBMCs are not affected by sex or gender, there are now easier dosing options
 for cisgender women and for people who are transgender and non-binary.
- Other studies show that everyone can now quick-start PrEP with a double dose (two pills) to be protected within two hours. In Canada we have not revised the PrEP guidelines and speak to your health care provider for updates

2:1:1 dosing sex once

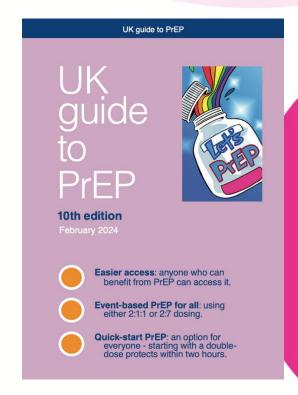


2:1:1 dosing can be used by anyone having insertive sex or receptive anal sex.

BEFORE SEX 2 PrEP pills 2 to 24 hours before sex. Total = 4 pills. WED THU FRI SAT SUN MON TUE WED

If you might have sex on Thursday take a double dose at least two hours before you have sex.

Then take a single pill for the next **two** days. This should be roughly 24 hours and 48 hours after the first double dose.



UK Guide to PrEP 2024

2: 1: 1 dosing more sex



If you have sex over a few days, keep taking a pill each day. Continue for two days after the last day you have sex.

BEFORE SEX AFTER SEX 2 PrEP pills 2 to 24 1 PrEP pill every day you have sex, then every day hours before sex. for two days after. FRI SUN MON TUE WED THU SAT WED **FINAL** DOSE

If you have sex over several days continue to take a single pill every day you have sex at around the same time.

Then after you stop having sex, take daily PrEP for the next two days.

2: 7 dosing

Start with a double dose before sex and then take daily PrEP for seven days after sex, at roughly the same time each day.

3. Event-based 2:7 dosing

2:7 dosing is sometimes needed by cis women and trans and non-binary people having receptive vaginal/frontal sex.

BEFORE SEX

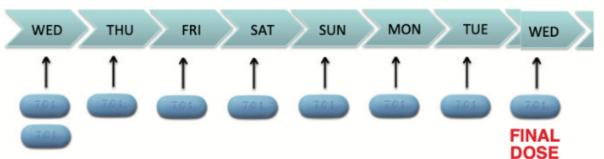
2 PrEP pills 2 to 24 hours before sex.

AFTER SEX

1 PrEP pill every day for seven days.

Total = 9 pills.





If you are a cisgender woman, or are transgender or non-binary, having receptive vaginal or frontal sex might need daily PrEP to continue for seven days.

This is for situations when you didn't take at least four doses of PrEP the previous week.





- GAY MEN'S SEXUAL HEALTH ALLIANCE
- Inquire into subjective and relational motivators for PrEP usage beyond selfperceived risk
 - (1) what it's like to be someone on PrEP
 - (2) an environment of changing sexual norms
 - (3) the continued importance of education
- "PrEP use is associated with their sense of belonging, trust, and security about their sexuality."
- "They also identified the most relevant aspects of the medication (e.g., side effects, adherence, and awareness) to their lives."

The Prep –Stigma Paradox: Learning from Canada's SERVEL BEALTH ALLIANCE First Wave of Prep Users (n=16)

- Participants were on PrEP for at least one year (Nov. 2014-June 2016)
- Sex-stigma emerged: a complex theme of PrEP use
 - PrEP-related stigma (concealment and stigma from friends, family, and sexual partners)
 - PrEP- a tool for combating HIV-related stigma (some men said that they no longer discussed HIV status with sexual partners)
 - PrEP as illuminating structural stigma (to unmasking stigma related to sex and sexuality)
- For some participants, PrEP has allowed
 - for liberating sex and a self-described return to normalcy-normal
 - exciting, pleasurable sex that was no longer reliant on condom use
 - Prepuse led them to experience stigmatizing reactions within their social and sexual networks, while also helping to remove stigma, shame, and fear related to HIV, sexuality, and sex with gay men living with HIV

Grace et al. (2018). DOI: 10.1089/apc.2017.0153



PrEP Whores and HIV Prevention

Use of PrEP has created opportunities and challenges for GBMSM

Before PrEP	PrEP use
Behavior change	Slut shaming/not responsible/ copout from using condoms, judgements
Population specific social marketing	Dirty
Needle exchange, condom distribution	Mourning loss of condoms
STIs /clean	Reclaim the inner whore/slut
Fear of HIV	Freedom to have sex 24/7 regardless of sexual partner(s) HIV status, not all sex is anal sex



PrEP, STIs and check up

- Strongly encourage GBMSM discontinuing PrEP to remain engaged in sexual health services. (McLean et al. (2022). AIDS Patient Care and STDs)
- "If someone uses PrEP, it is often automatically assumed that sex will be condomless." (Rotsaert et al. (2022). AIDS Patient Care and STDs)
- Shigella: "The emergence of multidrug-resistant (resistance to more than three classes of antibiotics) and extensively drugresistant (XDR, resistance to all but two classes of antibiotics) strains of Shigella is a global public health concern. (XDR: extensive drug resistance)
- Most cases in this outbreak were HIV-negative MSM taking daily PrEP." (Re: Out of ST, extensively drug resistant Shigella. The Lancet. July 2022)

- Oropharyngeal gonorrhoea: (n=2, 546 MSM). Largest study on exposures to the oropharynx from the three key anatomical sites of their partners, (mouth, penis, anus).
- "Results: oropharyngeal gonorrhoea was associated with exposure to a partner's mouth through kissing, and rimming," but not for penis through fellatio.
- Gonococcal infections at the oropharynx and anorectum are often asymptomatic, kissing and rimming can contribute to a proportion of oropharyngeal infections."
- Men currently taking PrEP, were significantly more likely to have oropharyngeal gonorrhoea. (Re: Kissing, fellatio, analingus risk factors for oropharyngeal gonorrhea in MSM. The Lancet.2022)

Danish study finds that STI rates in gay men increase before they start PrEP, not after

- N=1326 gbMSM and trans
- The study was able to chart the annual incidence of the three bacterial STIs, chlamydia, gonorrhoea and syphilis, in people attending sexual health clinics both before and after they started PrEP
- Found that they had more than twice as many (115% more) STI diagnoses while on PrEP than they had some time before starting it.
- However, it also found that much of this increase in diagnoses was due to increased testing.
- However, people took three times as many STI tests after starting PrEP than before.

- The study "does not imply that PrEP causes risk compensation," say the authors.
- "Rather, it indicates that PrEP is being given when the risk of STIs is increased, i.e. when it is most needed."
- They add that "this makes PrEP programmes a critical point of intervention [in which] it is crucial so provide a safe and supportive environment that includes comprehensive sexual health consultation."



- 1. Gonorrhea: Health Promotion for Gay Bi Men who have sex with Men https://gmsh.ca/wp-content/uploads/2023/10/GMSH-Fact-Sheet-Gonorrhea-2023-final.pdf
- 2. Syphilis: Health Promotion for Gay Bi Men who have sex with Men https://gmsh.ca/wp-content/uploads/2023/10/GMSH-Fact-Sheet-Syphilis-2023-final.pdf
- 3. Chlamydia: Health Promotion for Gay Bi Men who have sex with Men https://gmsh.ca/wp-content/uploads/2023/10/GMSH-Fact-Sheet-Chlamydia-2023-final.pdf



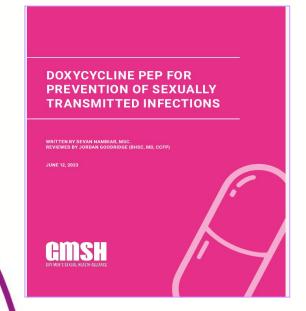
Doxycycline PEP for prevention of STIs

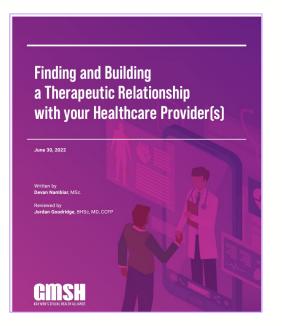
Doxycycline PEP for prevention of sexually transmitted infections

• https://gmsh.ca/wp-content/uploads/2023/06/GMSH-Pep-for-STI-Prevention-2023-1.pdf

Finding and Building a Therapeutic Relationship with your Healthcare Provider

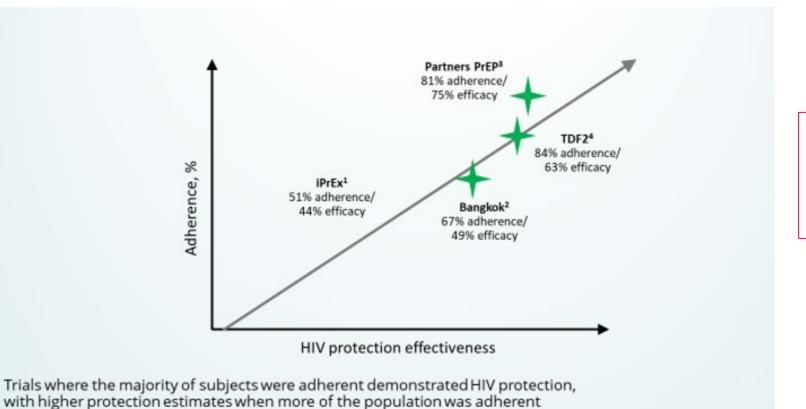
• https://gmsh.ca/wp-content/uploads/2022/09/GMSH-Finding-A-HCP-E-2022.pdf











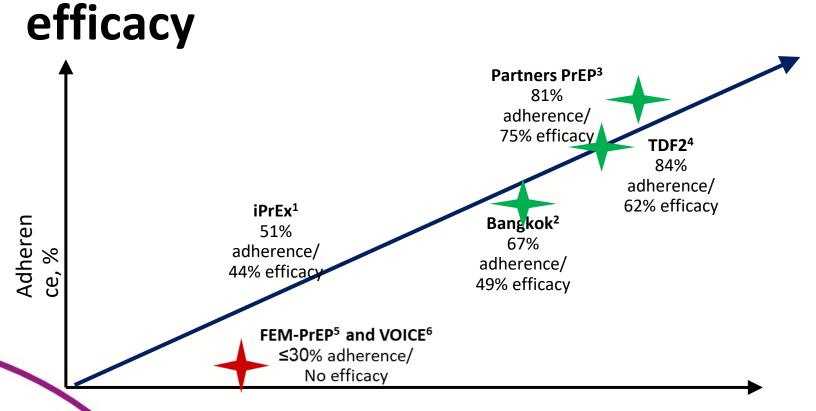
Key message: When drug levels were high, effectiveness was high. Adherence= prevention

Grant R, et al. N Engl J Med 2010;363:2587-99.
 Choopanya K, et al The Lancet. June 13, 2013.
 Baeten J, et al. N Engl J Med 2012;367:399-410.
 Thigpen M, et al. N Engl J Med 2012;367:423-34.

Credit: Dr. Kevin Woodward, MD, FRPC
Associate Professor, Department of Medicine, Division of Infectious Diseases, McMaster University

PrEP: Low adherence correlates with poor





Credit: Dr. Kevin Woodward, MD, FRPC Associate Professor, Department of Medicine, Division of Infectious Diseases, McMaster University

HIV protection effectiveness

Trials where only a minority of subjects were adherent did not/could not demonstrate HIV protection





PrEP uptake has been suboptimal in Canada and globally

- PrEP use has increased with favorable policies, but uptake of PrEP remain far below guidelines recommendation
- A recently developed point-of-care (POC) immunoassay for quantifying tenofovir levels in urine has enabled real-time monitoring of PrEP adherence within the previous 48–72hours
- During the appointment, the nurse requested client to provide a urine sample, which was tested in their presence.
- The test uses a competitive assay in its prototype form, that two lines on the test strip indicated a positive test for non-adherence (i.e. absence of tenofovir).
- In contrast, one line signified a negative test result (drug detection).
- Based on this drug-level feedback, individualized PrEP adherence counselling was tailored based on the participants' test results, including positive reinforcement to foster adherence and a "de-shaming" communication approach when non-adherence was identified.

Trends in HIV pre-exposure prophylaxis use in eight Canadian provinces, 2016-2020, and 2022



- In 2020
 - More than 70% of PrEP prescriptions were prescribed by primary care providers
 - 35% of people on PrEP were 25-35 years of age
 - The number of people taking PrEP aged 18-24 years increased by 1,800% between 2016 and 2020 (From 82 to 1,559 individuals taking PreP)
- More than two thirds of PrEP prescriptions were paid for by private insurance
 - The number of people on PrEP increased 4x from 2016 to 2020

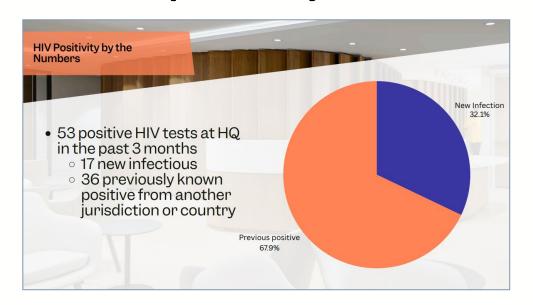


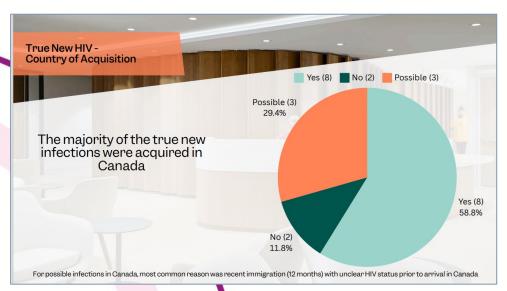
Pre-exposure prophylaxis for HIV: effective and underused. Hempel et al. (2022).

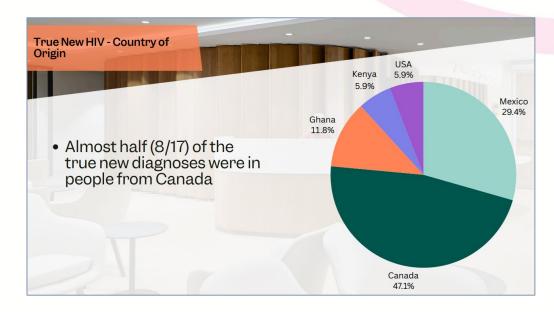
CMAJ September 06, 2022 194 (34)E1164-E1170; DOI: https://doi.org/10.1503/c

maj.220645

HIV Testing and Positive Cases Review March/April/May 2024 with low to no PrEP use in Toronto.







- Most individuals with new diagnoses were between
 26 35 years old
- Only 18% reported previous PrEP use; reasons for stopping usually cost related

Source: HQ, 2024





- PARTNER 2 (2010-2017): 75 sites in 14 European countries (n=972 gay couples)
- Goal of study: provide precise estimates of transmission risk in gay serodifferent partnerships.
 - Risk of HIV transmission through condomless sex in serodifferent gay couples with the HIVpositive partner taking suppressive antiretroviral therapy
 - CAI reported: 76,088 times. (n=288 (37%) of 777) HIV-negative men reported condomless sex with other partners
- 15 new HIV infections occurred during eligible couple-years of follow-up, but not in couple transmissions
 - resulting in an HIV transmission rate of zero
- Research evidence: HIV transmission in gay couples through condomless sex when HIV viral load is suppressed is effectively zero.
 - Our research support U=U.



PrEP cost at a glance

Drug	Efficacy	Dosage	Cost monthly	Side effects (mild to temporary)	Payment options
Truvada (TDF+FTC)	99%	300mg/200 mg	\$1,039.00	nausea, vomiting, diarrhea, headache, weight loss, and dizziness	Private insurance, Trillium, ODSP, OW, Non-Insured Health Benefits (NIHB)for Indigenous persons, cross-border shopping (CBS)
Descovy (TAF+FTC)	99 % (Prodrug)	25mg/200 mg	\$939.00	nausea, vomiting, diarrhea, headache and dizziness	Private insurance, Trillium, ODSP, OW, NIHB, CBS
Generic (TDF+ FTC)	99%	300mg/200mg	\$ 253.00	nausea, vomiting, diarrhea, headache, weight loss, and dizziness.	Private insurance, Trillium, ODSP, OW, NIHB, CBS

Health Canada approves Cabotegravir (Apretude) the first long-acting injectable for HIV prevention

- Canada May 13, 2024. A long-acting formulation of Cabotegravir has been approved for HIV prevention.
 This drug has been highly effective in clinical trials at significantly reducing the risk of HIV
- When Apretude becomes available in Canada, people who are interested in and medically eligible for getting Apretude injections (and after discussion with their HCP) have two options:
 - They can start a course of pills (cabotegravir 30 mg daily) for up to a month then switch to injections.
 - o If doctor and patient agree, they can begin an injection of Apretude and skip the use of the oral formulation.
 - Apretude (ERF) is given first as two initiation injections —one month apart, then every two months thereafter
 - Patients can either start their treatment with Apretude or take oral cabotegravir (Vocabria) for four weeks to assess how well they tolerate the drug.
 - Side effects for Apretude: include injection site reactions, headache, pyrexia (fever), fatigue, back pain, myalgia and rash



PIP – PEP in Your Pocket

- PIP is PEP-In-Your-Pocket: offer patients a month's supply of PEP before a potential HIV exposure
- Persons have it on hand if there is a HIV exposure rather than having to go to the emergency room
- Start as soon as possible and to be taken within 72 hours of exposure for 28 days
- PIP will be effective for hard-to-reach communities
- People who inject drugs or Party n Play
- Sex worker
- PIP involves less appointments with a health care provider
- Only involves daily use of the medication when such an exposure occurs.

CATIE: https://www.catie.ca/catie-news/a-novel-hiv-prevention-approach-called-pip-in-cases-with-infrequent-exposure-to-hiv

Biktarvy useful for HIV post-exposure prophylaxis (PEP)



- Some HIV drugs taken within 72 hours of a potential exposure reduce the risk of infection
- Researchers in Boston tested the HIV medication Biktarvy as post-exposure prophylaxis (PEP)
- The study found Biktarvy was well tolerated as PEP with no HIV transmissions
- Bictegravir 50 mg
- TAF (tenofovir alafenamide) 25 mg
- FTC (emtricitabine) 200 mg
- "PEP is meant as an emergency measure. For people with ongoing exposures to HIV, discussion
 with a healthcare provider about options to minimize the risk of HIV infection, including the use of
 HIV pre-exposure prophylaxis (PrEP), is a prudent course of action."

Boston study finds Biktarvy useful for HIV post-exposure prophylaxis (PEP) (CATIE)

Blood donation and PrEP and PEP



- "Use of PrEP may interfere with testing for HIV by delaying seroconversion or giving unclear results in a positive donor. For this reason, it is important that donors who have taken PrEP in the previous three months are not accepted to donate, even if they do not have another blood safety risk."
- Here is some clinical rationale- as PrEP does not provide a clear result of of HIV testing " "The
 clinical implications [of the findings] are currently unknown," Custer said. "The potential or cause
 for concern is that ART and PrEP by definition are taken to alter the course of HIV infection; thus,
 the use of ART or PrEP could impact our ability to detect HIV infection in donated blood because
 blood tests for HIV measure the presence of viral RNA or antibodies to HIV infection."

Pre- and Post-Exposure Prophylaxis for HIV prevention (transfusionguidelines.org)

https://www.healio.com/news/hematology-oncology/20200728/blood-donations-by-people-taking-drugs-to-treat-prevent-hiv-could-be-cause-for-concern



Summary

- PrEP has a 99% efficacy to prevent HIV-infection
- Adherence to PrEP is crucial to prevent HIV-infection
- Client centered care in PrEP use: daily, 2-1-1, injectable
- Testing for STIs is recommended if sexually active
- Baseline bone density scan
- There are psychosocial issues of PrEP use in GBMSM communities
- Access to range of PrEP prescribers across Ontario



Contact info

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- PrEP and drug resistance. https://www.aidsmap.com/about-hiv/prep-and-drug-resistance
- Excretion of drugs in the kidney https://slideplayer.com/slide/13070979/
- Most switches to *Descovy* PrEP are probably unnecessary and some may be harmful (2021).
 https://www.aidsmap.com/news/oct-2021/most-switches-descovy-prep-are-probably-unnecessary-and-some-may-be-harmful
- Trans and cis women and men all have similar levels of PrEP drugs in blood, directly observed
 dosing study finds | aidsmap
- PrEP does not lower hormone levels in young transgender people, but lower PrEP levels seen in some transgender women | aidsmap



References

- Tan. D. MD. (2022). The Future of PrEP is now! The future of PrEP is now! | CATIE Blog
- WHO recommends the dapivirine vaginal ring as a new choice for HIV prevention for women at substantial risk of HIV infection
- <u>The HIV Prevention–Certified Provider Program: A Training and Certificate Program Designed to Improve Competencies and Expand the HIV Prevention Workforce (peerview.com)</u>
- Transition Related Surgeries (TRS): https://www.womenscollegehospital.ca/care-programs/surgery/transition-related-surgeries/
- FAQ TRS: https://camh.ca/-/media/files/transrelatedsurgery-faq-en-pdf.pdf
- Trans health knowledge base: https://www.rainbowhealthontario.ca/trans-health-knowledge-base/category/transition-related-surgeries-trs/



Resources

- Tan et al. (2018). Canadian guideline on HIV pre-exposure prophylaxis and nonoccupational postexposure prophylaxis (updated version, 2018).
 https://www.cmaj.ca/content/cmaj/189/47/E1448.full.pdf
- CMAJ Poscasts on PrEP interview with Dr. Darrell Tan on Canadian guideline on HIV PrEP https://soundcloud.com/cmajpodcasts/170494-guide
- British Columbia Centre of Excellence in HIV. (2020). Guidance for the use of Pre-exposure Prophylaxis (PrEP) for the Prevention of HIV Acquisition in British Columbia
- HIV Pre-exposure prophylaxis use in Canada. Volume 43-12, December 7, 2017: Can we eliminate HIV?



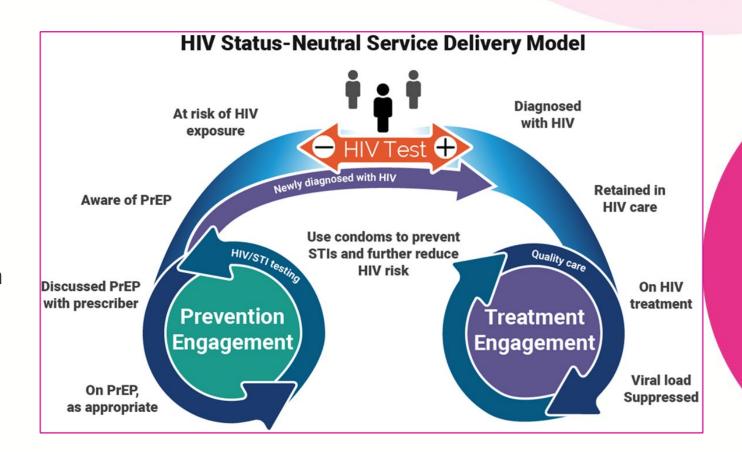
Bone Mineral Density (BMD) Testing

- Osteoporosis is a disease characterized by low bone mass leading to fragile bones and increased risk of fractures. BMD testing measures bone loss due to osteoporosis and helps the patient and physician decide the risk of future fractures, determine the need for medical treatment and monitor the success of existing treatment.
- Ontario Diagnostic Centre https://www.ontdc.ca/what-to-know-about-bone-density-testing/
- https://www.ontario.ca/document/guide-programs-and-services-seniors/health-and-well-being#section-10
- Ontario Association of Radiologist https://oarinfo.ca/patient-info/radiology-medical-services/bone-mineral-densitometry
- Bone Mineral Density test. https://osteoporosis.ca/bone-mineral-density-testing/



Status Neutral Approach to HIV

- "A status-neutral approach to HIV care means that all people, regardless of HIV status, are treated in the same way. It all starts with an HIV test.
- Any result, positive or negative, kicks off further engagement with the healthcare system, leading to a common final goal, where HIV is neither acquired nor passed."



Re: https://blog.catie.ca/2019/11/04/an-hiv-status-neutral-paradigm-shift/

U=U: Undetectable = Untransmittable



- An overwhelming body of clinical evidence has firmly established the U=U, concept as scientifically sound.
- "U=U means that people with HIV who achieve and maintain an undetectable viral load—the
 amount of HIV in the blood—by taking antiretroviral therapy (ART) daily as prescribed cannot
 sexually transmit the virus to others." NIH
- From Health Canada: <u>HIV: Undetectable = Untransmittable (U=U) Canada.ca</u> The science behind Undetectable = Untransmittable, its benefits in addressing HIV, and how to sprea
- HIV is sexually untransmittable when viral load is undetectable.
 https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(23)01519-2/a
- Broyles et al. 2023. The risk of sexual transmission of HIV in individual with low-le systemic Review. https://www.thelancet.com/journals/lancet/article/PIIS0140-6
 2/fulltext
- WHO: New WHO guidance on HIV viral suppression and scientific updates relea

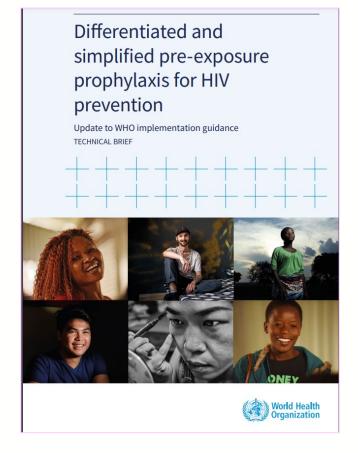
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WHO



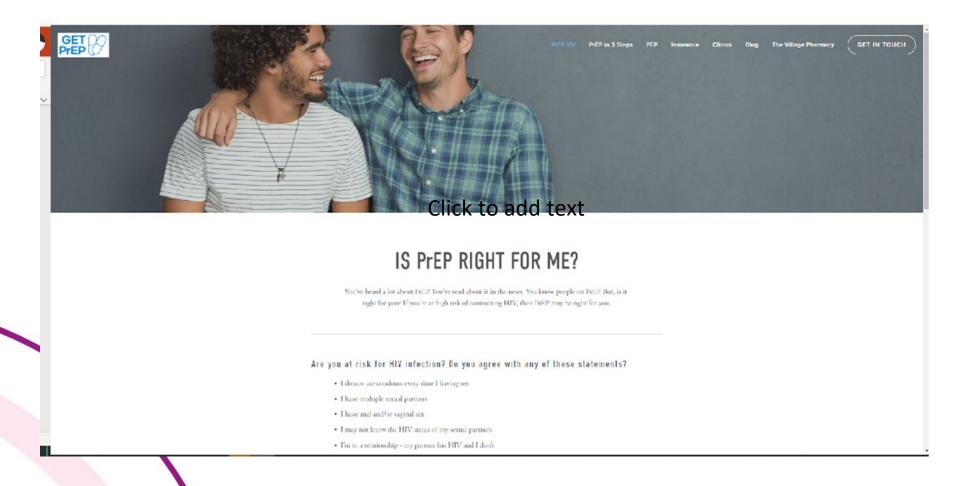
- WHO launched new implementation guidance for simplified and differentiated service delivery of pre-exposure prophylaxis (PrEP) addressing HIV, and how to spread the word.
- WHO Implementation guidance

https://www.who.int/news/item/26-07-2022-who-launched-new-implementation-guidance-for-simplified-and-differentiated-service-delivery-of-prep





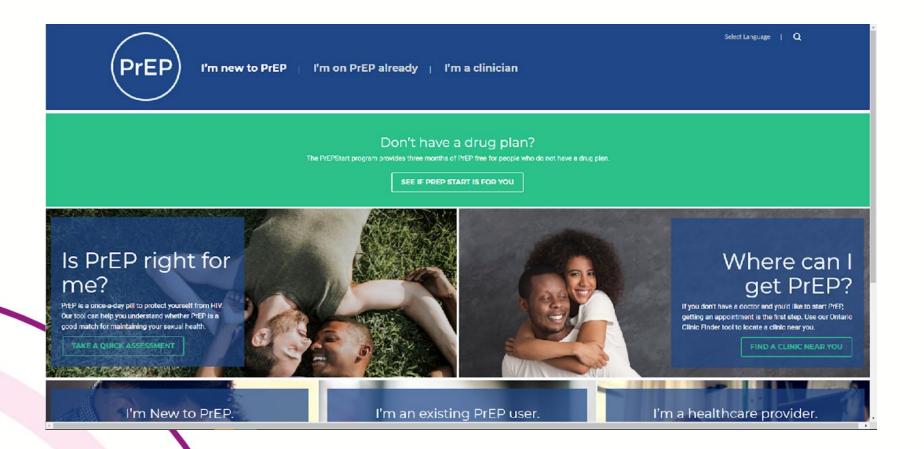
Is PrEP Right For Me?



https://www.get-prep.com/is-prep-right-for-me

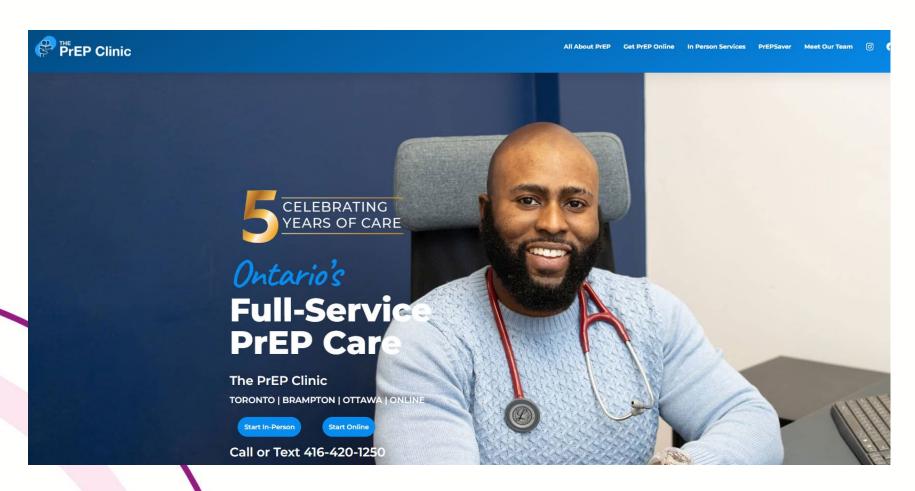


https://ontarioprep.ca/





The PrEP Clinic



https://www.prepclinic.ca/

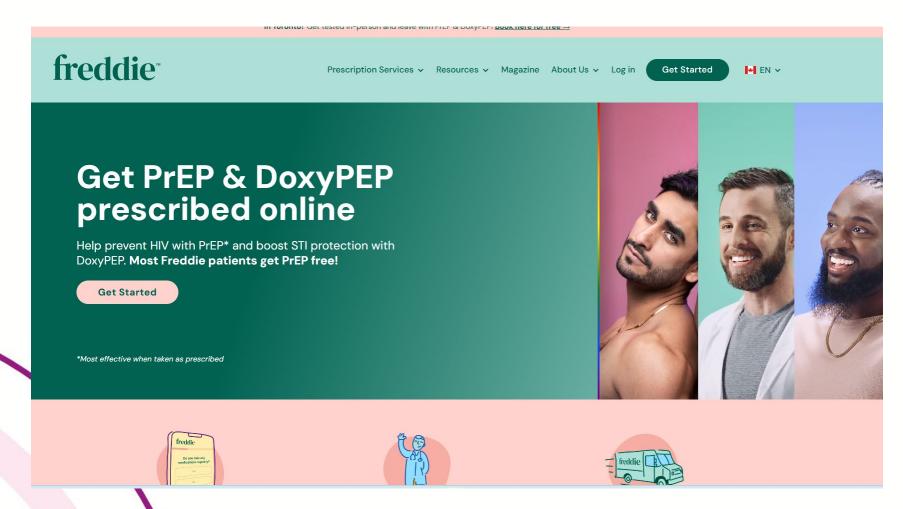


Medsexpert



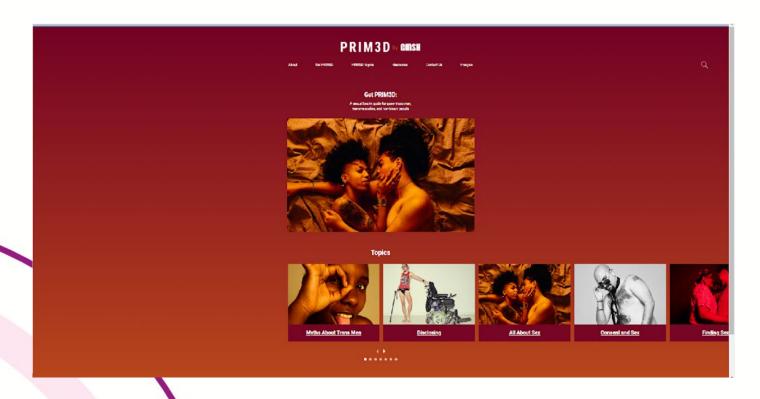


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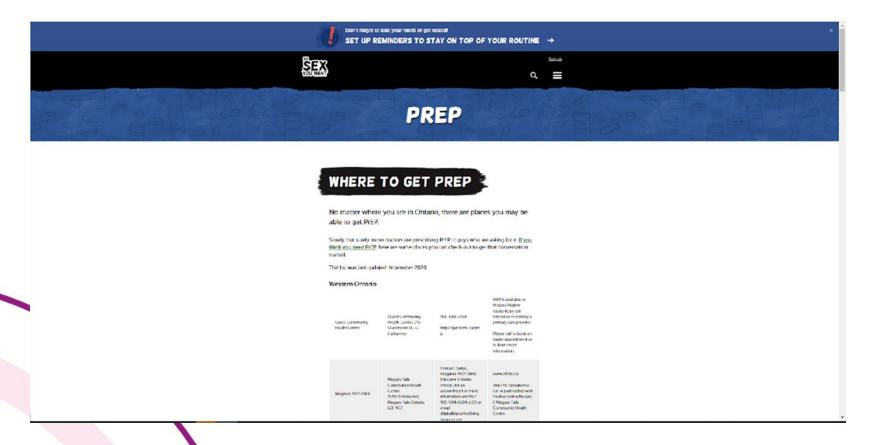
https://www.gofreddie.com/

Prim3D: A sexual health guide for queer transmen, trans masculine, and non-binary people



https://getprimed.ca/

https://thesexyouwant.ca/prep/where-to-sexual Health get-prep/





Newcomers, international students

- Hello Ontario http://helloontario.info/
- It depends on the insurance plan. If they do not have coverage, international students or those here on a visitors visa/work visa without OHIP can access medications through ordering online.
- Here is a guide that may be helpful: Guide for Visitors to Canada: https://daviebuyersclub.wordpress.com/home/guide-for-visitors-to-canada/
- Payment options: https://ontarioprep.ca/for-health-care-providers/pay/

OHTN International Student Resource Guide

• https://hqtoronto.ca/wp-content/uploads/OHTN-International-
Student-Resource-Guide.pdf

• https://hqtoronto.ca/international-student-resources/







