Clinical Pearls & Background Information

- PrEP reduces HIV acquisition (e.g. by 90% in MSM/TGW),
 & can be used with other risk reduction strategies.
- If indicated, all prescribers may order emtricitabine/ tenofovir disoproxil fumarate, usually one tablet daily, but on-demand dosing is an option for some MSM.
- Emtricitabine/ tenofovir alafenamide may be useful e.g. eGFR<60, fracture hx, but access limited (coverage/\$)
- PrEP is well tolerated & prescribed at 3 mos intervals with monitoring for adherence, AE, HIV, STIs, arenal function, also HCV & pregnancy if applicable (see Table 2).

DESCOVY PDA'19, CDN'20

200/25mg tab **X** ⊗ ≥35kg (PrEP)

- ~2500 new cases of HIV reported per year in Canada & ~200 in SK. 6-8
- Which populations have an ↑ incidence of HIV diagnoses?
 - Canada: ~55% occur in gay/bisexual/MSM. Other: those from HIV endemic countries, Indigenous peoples, sex workers, & TGW.⁶⁻⁸
 - Saskatchewan: ~67% occur in people who inject drugs.
- What is pre-exposure prophylaxis (PrEP)? PrEP is a proactive prevention strategy where HIV-negative persons at ↑, ongoing risk take a once-daily tablet before & after potential HIV exposure to prevent transmission in combo with others strategies e.g. opioid agonist tx, needle exchange, safer injection practices, consistent condom use, HIV screening.

Table 1. Likelihood of HIV acquisition depends on: modified from CMAI'17

(A) Likelihood the person (i.e. the source) may transmit HIV

High-risk HIV viral load >40 copies/mL, HIV status unknown & from population with ↑HIV prevalence (e.g. PWID, see left for more populations)

Low-risk HIV viral load <40 copies/mL & concomitant STI at time of exposure

Negligible HIV viral load <40 copies/mL x6mos & no known STIs many stable, closed couples

(B) Likelihood of HIV transmission based on exposure type

High-risk receptive anal (1.38% / act), needle sharing (0.63% / act)

Mod-risk insertive anal/vaginal, receptive vaginal (≤0.11% / act)

Low-risk oral sex, oral-anal contact, sex toys, blood on compromised skin

Test	Baseline (day 0)	@ 1 month	q 3 month
HIV test & assess for		* **	
acute HIV-related		monitor for seroconversion	
signs/symptoms*			
Hepatitis A serology			
Hepatitis B serology			
Hanatitis C saralagy		q12mos; 个frequency if ongoing	
Hepatitis C serology	1	e.g. shared injection drug supplies	
STIs e.g. gonorrhea, syphilis, chlamydia ± rectal/throat swabs if applicable	•	-	✓
SCr, eGFR 🤌		- / optional expert opinion	
Urinalysis r/o kidney dx			
CBC			
Pregnancy as appropriate		-	✓
PrEP indication see step 1	✓ psychological benefits may be important for some		
PrEP AEs/tolerability	-	✓	
PrEP adherence	-	✓	

Acute HIV related illness/seroconversion: flu-like sx ≤12wks e.g. fever, myalgia, HA,
HS sweats, pharyngitis → clinical decision, may defer PrEP & repeat test 1-3wks.

If recent (≤72hr)↑ risk exposure: refer for nPEP (RxFiles: HIV) and assess for PrEP.

**have a low threshold for ordering an HIV test if patient taking PrEP reports having a

acquisition, encourage condom use.

off-label and unstudied.

Note: On-Demand dosing with **DESCOVY** is

An Approach to Pre-exposure Prophylaxis (PrEP) consider both past and future anticipated risk e.g. sex & drug use

Step 1: Identify people who are HIV-negative at increased chance of acquisition i.e. Prep indication (nPEP if ↑risk exposure ≤72hr)

Men who have sex with men (MSM) & Transgender women (TGW)	 HIV Incidence Risk Index for MSM (HIRI-MSM), score ≥10=2%/yr & score >25=7%/yr risk of incident HIV.9-10 STI (syphilis or rectal bacterial gonorrhea or chlamydia), especially if diagnosed in the last 12 months. Use (≥1) of non-occupational post-exposure prophylaxis, associated with ~7%/year risk of incident HIV.11 			
(IGW)	 Ongoing sexual relationship with HIV-positive individual(s) with risk of HIV transmission (see Table 1). 			
People who are	People who are HIV-negative in serodifferent relationship(s) reporting condomless vaginal/anal sex where			
heterosexual	there is non-negligible risk of HIV transmission (see Table 1). Includes attempts to conceive with a HIV-positive person			
People who inject drugs RXFiles Patient Q&A: injecting drugs	People who are HIV-negative sharing injection drug equipment with a person who has non-negligible risk of HIV transmission. May consider ARCH-IDU Risk Score (≥46 indicates further assessment).¹²			

PrEP is not indicated in serodifferent (e.g. 1 partner HIV-positive, 1 partner HIV-negative) closed relationships where the person who is HIV-positive is on HIV meds & there is negligible risk of HIV transmission i.e. viral load <40 copies/mL or undetectable x 6 mos & no known STIs.
 Undetectable=Untransmittable.

Step 2: Conduct baseline investigations see Table 2, physical exam is ususally not required.

- CI: HIV-positive; 🔰 tenofovir TDF eGFR <60mL/min, tenofovir TAF eGFR <30mL/min. Caution: HBV. Refer: 🤰 eGFR <60mL/min; pregnancy
- Screen (as time allows, doesn't preclude PrEP): mental health e.g. depression pg 185; substance use disorder pg 218 e.g. AUD pg 221, OUD pg 136
- <u>Vaccines</u>: offer hepatitis A, hepatitis B vaccine if non-immune, & HPV if unvaccinated see <u>RxFiles Vaccines Chart</u> pg 79. Refer to public health. **Step 3: Prescribe PrEP & Provide Education** see <u>RxFiles PrEP Infographic</u>.
- Usually, prescribe <u>daily dosing</u> TRUVADA, g 1 tab daily x 1 month initially, (once follow up done, then prescribe x 3 months i.e. 2 refills).
 - <u>Daily dosing method for MSM/TGW, people who are heterosexual, & PWID</u>: for ongoing prevention from exposures.
 ✓ most robust evidence, daily admin habit, regular sexual activity/drug use ✗ off-label for PWID, ↑pill burden, ↑drug exposure, ↑cost.
- Most robust evidence, daily admin habit, regular sexual activity/drug use A on-label for PWID, 1 pin burden, 1 drug exposure, 1 cost.
 On-Demand method for MSM only, off-label: for prevention from 1 sexual encounter (see dosing below).
- ✓ occasional sexual activity, ↓pill burden, ↓drug exposure (?benefit CKD), ↓cost ✗ off-label, ?remembering to take pills, loading dose ↑GI.

 If ongoing risk, may convert to daily method after taking on-demand loading dose. Expert Opinion, off-label Must take for at least 2 days after last sexual encounter.

Step 4: Follow-up: in clinic/phone at 1mos & then q3mos, see Table 2. If PrEP is not indicated i.e. person no longer has an ↑ chance of

MSM/TGW: daily non-inferior to TRUVADA. DISCOVER

Consider if CI or caution with TRUVADA e.g. eGFR

<60 or hx of fractures/osteoporosis (ensure coverage)

few days of sore throat, mono-like illness, or rash. Expert Opinion								
Generic/TRADE	Comments	Adverse Events AE / Contraindications CI / Drug Interactions DI / Monitoring M (see Table 2 above)	Dosing (see Step 3 above)	\$/30c				
NUCLEOSIDE / NUCLEOTIDE REVERSE TRANSCRIPTASE INHIBITOR (NRTI) aka "nuc": prevent HIV acquisition by inhibiting HIV reverse transcriptase resulting in viral HIV DNA chain termination.								
Emtricitabine / Tenofovir disoproxil fumarate (FTC/TDF) TRUVADA, g → FDA'12, CDN'16 200/300mg tab FDA: ≥35kg PrEP; CDN: ≥18yr -generic → SPDP, NIHB: open benefit with no prescriber limitation & no cost to patient -TRUVADA → SPDP: patient pays \$20/tablet	who are heterosexual. Off-label for PWID, & ondemand dosing method, but guideline supported. • MSM/TGW: TRUVADA daily vs placebo, ↓ HIV transmission NNT=36/1.2yrs (3% vs 5.8%; HR 0.53).	AE: Common: HA, GI (abdo pain, flatulence, N/V/D; may take HS or cc; ↑ nausea with on-demand NNH=14/9mos 7% vs 1%, daily dose ~2%), & fatigue are transient (~1-2wks); ≤2% stop PrEP tx due to AE. DESCOVY: ↑lipids, Wt (1kg). TRUVADA: ?clinical relevence ↓eGFR 1mL/min/yr & ↓BMD usually rev upon D/C; routine BMD not recommended, ensure adequate Ca++, Vitamin D, exercise. CI: see above. Caution: HBV (potential flare if D/C, daily dosing preferred); other STIs; adherence (required: MSM/TGW ≥4 doses/wk; others ≥6 doses/wk); >50yrs (less studied); TRUVADA: renal-impacting comorbidities e.g. T2DM, heart failure, HTN;	On-Demand or "2-1-1" method (MSM only off-label): 2 tabs taken together 2-24 hours before sexual activity, then 1 tab daily until 2 days after last sexual activity. IPERGAY	\$860 TRUVADA 4, \$140 { (~15 tab: mos !PERG				
Emtricitabine / Tenofovir alafenamide (FTC/TAF)	✓ PrEP: daily dosing for MSM/TGW. Off-label for PWID or are heterosexual, & on-demand dosing.	↑ fracture/osteoporosis (consider DESCOVY); pregnancy: TRUVADA preferred. DI: ↓tenofovir: estrogens/androgen blockers transfeminine; ↑TRUVADA: hepatitis	Daily method: 1 tablet once daily. DISCOVER	\$863				

meds; TRUVADA: nephrotoxins e.g. regular/high-dose NSAIDs, valacyclovir;

No DI: methadone, SUBOXONE, EtOH, contraceptives. M: Table 2 above.

↓DESCOVY: P-gp inducers e.g. phenytoin; **↑DESCOVY**: P-gp inhibitors.

SHOULD I TAKE A PILL TO PREVENT HIV?

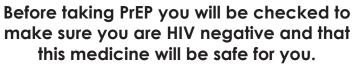


= 1 tablet once daily, it contains 2 medicines active against HIV



PrEP prevents HIV

from other sexually transmitted infections the way condoms do.



Regular follow-up with your health care team is important.

This includes blood work, testing for HIV & sexually transmitted infections, and follow-up appointments about every 3 months.



PrEP can decrease your chance of getting HIV by about 85-90% and it may even be

up to 99% effective

when used exactly as directed.





PrEP = Pre-Exposure Prophylaxis for prevention of HIV

* in men or trans women who have sex with men

It is usually prescribed as emtricitabine + tenofovir disoproxil fumarate or TRUVADA®.

It can also be prescribed as emtricitabine + tenofovir alafenamide or DESCOVY®, but this is less common and not free.

ARE THERE SIDE EFFECTS?

DOSING METHODS FOR MEN OR TRANS WOMEN WHO HAVE SEX WITH MEN

You may experience some side effects, but most people don't stop taking PrEP because of them.



Some people feel nauseous or sometimes even throw up. Others may get headaches.

After 1 to 2 weeks, most people find that these mild problems go away.



You can take medicines such as:

- dimenhydrinate GRAVOL® to help with nausea or - acetaminophen TYLENOL® to help with headache.



PrEP may impact how well your kidneys work, and your health care team will monitor this closely.



PrEP may change your bone strength, but once you stop the medication this usually goes back to normal.

The impact of PrEP on kidney function and bone strength may happen when taken over a long period of time (not immediately).



Check in with your pharmacist, as some medicines like ibuprofen $\mathsf{ADVIL}^{\circledR}$ or naproxen $\mathsf{ALEVE}^{\circledR}$ can interact with PrEP. Your pharmacist can also help you learn about calcium & vitamin D, and the importance of exercise for healthy bones.

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Adapted from Dr. Bradley Little, Spectrum Health

a) CONTINUOUS -

Taken once a day, every day.



You must take PrEP for 7 days in a row before you are protected during sexual activity.



continue...

b) ON DEMAND'

Taken as needed.

Sa



work properly.

DAY 1 = two tabs 2 to 24 hours before sexual activity 2 tabs Tues at 9 a.m. SEXUAL ACTIVITY Tues at 10 p.m.

For CONTINUOUS or ON-DEMAND*
dosing, you must continue to take
PrEP at least 2 days after your last
sexual activity in order for it to

* off-label prescribing

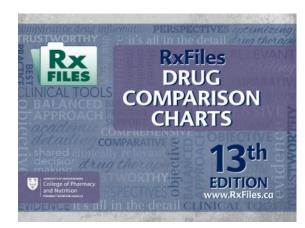
DAY 2 = one tab 24 hours after 1st dose 1 tab Wed at 9 a.m.

DAY 3 = one tab 48 hours after 1st dose 1 tab Thurs at 9 a.m.

Pre-exposure Prophylaxis (PrEP) for HIV: Drug Comparison Chart

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Complete Abbreviations: ♀=female ♂=male ♂=renal dosing may be required ✓=Health Canada Official Indication ✗ =non-formulary in Saskatchewan ⊗=non-formulary for Non-Insured Health Benefits (NIHB) admin=administration ☐=adverse events ARCH-IDU=Assessing the Risk of Contracting HIV — Injection Drug Users ARVs=antiretroviral AUD=alcohol use disorder BC-CfE=British Columbia Centre for Excellence in HIV/AIDS BMD=bone mineral density Ca*+=calcium CBC=complete blood count cc=with food CDN=Canadian Cl=contraindicated CKD=chronic kidney disease CMAJ=Canadian Medical Association Journal d=day D/C=discontinue(d) ☐=drug interaction dx=disease eGFR=estimated glomerular filtration rate EtOH=alcohol FDA=approved Food & Drug Admin FTC/TAF=emtricitabine/tenofovir alafenamide FTC/TDF=emtricitabine/tenofovir disoproxil fumarate g=generic GI=gastrointestinal HA=headache HBV=hepatitis B virus HCV=hepatitis C virus HIRI-MSM=HIV Incidence Risk Index for MSM HIV=human immunodeficiency virus HPV=human papillomavirus hr=hour HS=bedtime HTN=hypertension hx=history IAS=International Antiviral Society IM=intramuscular kg=kilogram min=minute mL=millilitres M=monitoring mo(s)=month(s) MSM=men who have sex with men NIHB=non-insured health benefits NNH=number needed to harm NNT=number needed to treat nPEP= nonoccupational post exposure prophylaxis NSAID=non-steroidal anti-inflammatory drugs N/V/D=nausea/vomiting/diarrhea OUD=opioid use disorder PrEP=pre-exposure prophylaxis PWID=people who inject drugs q=every r/o=rule out RRR=relative risk reduction SCr=serum creatinine SK=Saskatchewan SPDP=Sask. Prescription Drug Plan STI=sexually transmitted infection sx=symptoms T2DM=type 2 diabetes mellitus tab=tablet TGW=transgender woman/women tx=treatment USA=United States of America USPSTF=US Preventive Services Task Force yr(s)=year(s)

Online Extras:

HIV Incidence Risk Index for MSM HIRI-MSM: Available at: https://smartsexresource.com/health-providers/provider-tools/calculate-hiri-msm-score

Assessing the Risk of Contracting HIV – Injection Drug Users (ARCH-IDU): Available at: https://www.albertahealthservices.ca/assets/info/hp/srh/if-hp-srh-hiv-prep-guidelines.pdf, see appendix C, page 19.

Saskatchewan Resources:

- SK HIV Collaborative: https://skhiv.ca/
- PrEP Clinics
 - Regina HIV PrEP Clinic
 - O Call for more information or to book your PrEP consultation: 306-766-3935
 - Patient self-refer
 - Saskatoon OUTSaskatoon Sexual Health Clinic
 - Call for more information or to book an appointment: 306-244-7989
- University of Saskatchewan Student Wellness Centre

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