

PrEP Updates Newsletter

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Infectious Diseases Group Practice (IDGP) PrEP Clinic

Editors:

[Katherine Frasca, MD](#)

[Donna McGregor, NP](#)

[Christopher Schultz, MD](#)

[Alexa Van Epern, PharmD, MPH](#)

[Amanda Ahumada](#)

[Lisa Lawrence](#)

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Summary of Prior PrEP Newsletters

- PrEP stands for Pre-Exposure Prophylaxis, medication taken to prevent HIV
- There are two FDA approved medications for use as PrEP as daily fixed dose combination pills:
 - Emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg, FTC-TDF, Truvada®
 - Emtricitabine 200 mg/tenofovir alafenamide 25 mg, FTC-TAF, Descovy®
- [PrEP is a Grade A recommendation by the USPSTF](#) for at-risk populations for HIV prevention
- PrEP and associated medical costs can be minimal, even for uninsured patients, in Colorado
 - [Colorado PHIP Program](#) can cover PrEP medical visits & labs, STI testing/treatment
 - [Gilead Advancing Access Program and Copay Coupon Card](#) can cover medication costs
- IDGP TelePrEP program: virtual clinic visits with free home testing kits for Colorado residents
 - Includes access for uninsured patients through the Colorado PHIP Program
 - For more information call PrEP coordinator [Amanda Ahumada](#) at 303-724-8245

Sexually Transmitted Infection (STI) Screening Supply Shortage

- In our last edition, we covered the CDC's recommendations for STI screening and treatment in the time of COVID-19 <https://www.cdc.gov/std/dstdp/DCL-STDTreatment-COVID19-04062020.pdf>
- The CDC sent out another Dear Colleague Letter September 3rd addressing the national shortage of STI testing supplies, specifically for gonorrhea and chlamydia testing, see **Table 1 below** for recommendations

Did You Know? STIs can be a red flag for HIV risk

- **Syphilis** -about 20% of men become HIV + within 10 years of a syphilis diagnosis
- **Gonorrhea** – 1 in 15 MSM with a history of GC rectal infection become HIV+ within 1 year
- **Chlamydia** -Women with CT are at 2x higher risk of becoming HIV+



Truong H-HM, Pipkin S, O'Keefe KJ, et al. Recent infection, sexually transmitted infections and transmission clusters frequently observed among persons newly-diagnosed with HIV in San Francisco. *J Acquir Immune Defic Syndr.* 2015;69(5):606-609.

2. Centers for Disease Control and Prevention. STDs and HIV – CDC Fact Sheet. <https://www.cdc.gov/std/hiv/stdfact-std-hiv-detailed.htm>. Updated October 8, 2019

Table 1. Recommendations for prioritization of STI diagnostic testing by population at times of diagnostic test kit shortage

	Asymptomatic individuals	Men with symptomatic urethritis syndrome	Women with cervicitis syndrome	Women with vaginitis syndrome	Proctitis syndrome	Complicated STD syndromes (PID)	Contacts to GC and/or CT
Tier 1: Recommendations based on the 2015 CDC STD Treatment Guidelines and no CT/GC NAAT test shortages	<p>Screen women <25 years of age and women ≥25 years of age who are at risk at least annually for CT and GC</p> <p>Screen pregnant women <25 years of age and pregnant women ≥ 25 years of age at risk for CT and GC at first prenatal visit. Screening should be repeated at third trimester for women <25 years of age and/or at high risk</p> <p>Screen MSM by site of exposure for CT and GC at least annually and more often (every 3-6 mo) in individuals with persistent risk including MSM on HIV PrEP</p>	Test for CT and GC	Test for CT, GC, <i>Trichomonas vaginalis</i> (TV) and bacterial vaginosis (BV)	Test for TV, BV and Candida	Test for CT, GC, syphilis and herpes simplex virus	Test for CT and GC	Test for CT and GC

Tier 2: Approaches to consider when STI diagnostic test kits are limited	<p>Prioritize women <25 years of age; pregnant women <25 years of age; women ≥ 25 years at risk[#]; pregnant women ≥ 25 years of age at risk[#] and MSM</p> <p>Vaginal testing (women), rectal and pharyngeal* testing (MSM) for CT and GC</p>	<p>Gram or methylene blue stain to direct therapy; Urinalysis or urine leukocyte esterase testing can be considered to confirm urethritis but will not distinguish between GC and CT</p> <p>Reserve urine-based testing for persistent urethritis</p>	Vaginal or endocervical testing for CT and GC; Wet prep for BV and TV testing**	Perform wet mount for TV, BV and Candida	Rectal testing for CT and GC	Vaginal or endocervical testing for CT and GC	Treat for appropriate organism
Tier 3: Approaches to take when STI diagnostic tests kits are severely limited or not available	No screening	<u>See guidance in DCLs regarding syndromic management</u>					

MSW = men who have sex only with women

MSM = men who have sex with men

*Prioritize rectal over pharyngeal testing in MSM if test kits are limited

#e.g. those who have a new sex partner, more than one sex partner, a sex partner with concurrent partners or a sex partner who has an STI

#Prioritize women (including pregnant women) <25 years of age if test kits are limited

**If CT/GC NAAT sent and TV can be performed using the same test kit, TV NAAT could be considered

House Bill 20-1061:

On July 13th, 2020, Governor Jared Polis signed [House Bill 20-1061](#), which allows a pharmacist to prescribe and dispense HIV infection prevention medications pursuant to a standing order or statewide protocol so long as the pharmacist has fulfilled specific requirements. HIV infection prevention medications include both PrEP and PEP (post-exposure prophylaxis). The bill will be ready for full implementation by early 2021.

PrEP Drug Interactions	Truvada® (FTC/TDF)	Descovy® (FTC/TAF)
<p>Drugs affecting renal function* Ex: acyclovir, adefovir dipivoxil, cidofovir, ganciclovir, valacyclovir, valganciclovir, aminoglycosides, topiramate, high-dose NSAIDs or multiple NSAIDs. Examples of high-dose NSAIDs include ibuprofen 800mg QID, celecoxib 200mg BID, meloxicam 15mg daily. More complete high-dose NSAID list here.</p>	<p>Truvada and Descovy are eliminated from the body via glomerular filtration and active tubular secretion. Other drugs that are eliminated via tubular secretion may compete for elimination and may lead to increased concentrations of FTC, TDF, TAF, or co-administered drug. Monitor renal function.</p>	
<p>P-gp inhibitors* Ex: Clarithromycin, verapamil, ketoconazole, itraconazole</p>	<p>Increases TDF exposure, but okay to use if monitoring renal function.</p>	<p>Increases TAF exposure, but okay to use if monitoring renal function.</p>
<p>Strong P-gp inducers* Ex: Rifampin, rifapentine, oxcarbazepine, carbamazepine, phenobarbital, phenytoin, St. John's Wort</p>	<p>Okay to use. Only a small decrease in TDF is expected because the dose of TDF outweighs effect of efflux by P-gp.</p>	<p>DO NOT USE. Decreases TAF exposure. The dose of TAF is not enough to overpower P-gp inducers.</p>

*List of example drugs is NOT all inclusive. To see the full list, please go [here](#).

PrEP of the Future: Injectables, Implants & More

- HIV prevention products for pre-exposure prophylaxis are being developed beyond a daily pill regimen to include long acting injectables, implants, vaginal rings and more!
 - Many are in phase 2-3 clinical trials, anticipated to be available commercially in the coming years
 - These agents are not yet FDA approved or available outside a clinical trial
- Results of the [major HIV prevention study HPTN 083 on injectable PrEP was just presented at AIDS 2020 in July](#)
 - Injectable cabotegravir (every 2 months) was superior to daily FTC-TDF (Truvada) in this multi-country, randomized, double-blind, double-dummy placebo clinical trial in cisgender MSM/TGW
 - A second study of the same design, [HPTN 084](#), is currently being conducted in cisgender women in Africa
- See the infographic summary below for [future long-acting forms of HIV prevention in clinical trials](#):

LONG-ACTING FORMS OF HIV PREVENTION

For some people, long-acting forms of HIV prevention may be more desirable than a daily pill.

HIV prevention today — and in the future.

Taking an oral dose of the medication Truvada **once a day, every day** can prevent HIV infection.

NIAID-funded researchers are developing and testing **alternative HIV prevention products** that could be inserted, injected, infused or implanted from

ONCE A MONTH...

...TO ONCE A YEAR

in people who commit to use the products on an ongoing basis.

Monthly

Yearly



NIAID is funding research on 4 types of long-acting HIV prevention.

INTRAVAGINAL RING (IVR)



Polymer ring inserted into the vagina releases antiretroviral drug over time.

IMPLANT



Device implanted in the body releases antiretroviral drug over time.

INJECTABLE



Long-acting antiretroviral drug is injected into the body.

ANTIBODY



Antibody is infused or injected into the body.

How many products are under investigation?



dapivirine IVR
(MTN 034/REACH clinical trials)
tenofovir IVR (CONRAD)
Truvada IVR (Oak Crest Institute of Science)



cabotegravir (SLAP-HIV project)
dolutegravir (University of North Carolina)
tenofovir alafenamide (Oak Crest Institute of Science)
tenofovir alafenamide & emtricitabine
(Houston Methodist Research Institute)

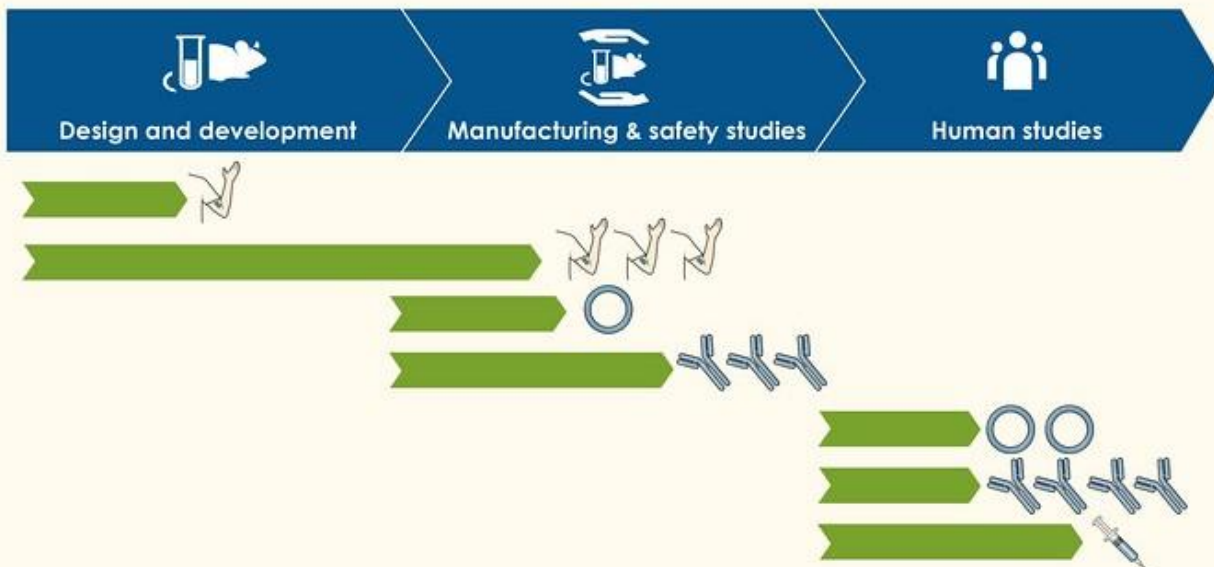


cabotegravir (HPTN 077, 083 & 084 clinical trials)



CAP256V2LS (NIAID VRC & CAPRISA)
N6LS (VRC 609 clinical trial)
PGT121.414.LS (NIAID)
Sanofi trispecific antibody (NIAID VRC & Sanofi)
VRC01
(AMP Studies, HVTN 116 & IMPAACT P1112 clinical trials)
VRC01LS (HVTN 116 & IMPAACT P1112 clinical trials)
VRC07-523LS
(VRC 610, HVTN 127/HPTN 087 & IMPAACT P1112 clinical trials)

At what stage is this research?



For more on the latest advances in HIV prevention research, visit: