PrEP Updates Newsletter
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Infectious Diseases Group Practice (IDGP) PrEP Clinic

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- Summary of Prior Newsletters
- STI Screening Supply Shortage
- Pharmacists corner: Colorado House Bill, Drug Interactions & PrEP

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
- 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+

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*Truvada in HIV, Table 6, (C)Gallia Co, at all major infections, sexually transmitted infections and
transmissible diseases, properly treated among patients who are infected with HIV in San Francisco, "Afric.

B. Centers for Disease Control and Prevention. STIs and HIV – CDC/17/19004.
Table 1. Recommendations for prioritization of STI diagnostic testing by population at times of diagnostic test kit shortage

<table>
<thead>
<tr>
<th>Tier 1: Recommendations based on the 2015 CDC STD Treatment Guidelines and no CT/GC/NAAT test shortages</th>
<th>Asymptomatic individuals</th>
<th>Men with symptomatic urethritis syndrome</th>
<th>Women with cervicitis syndrome</th>
<th>Women with vaginits syndrome</th>
<th>Proctitis syndrome</th>
<th>Complicated STD syndromes (PID)</th>
<th>Contacts to GC and/or CT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screen women &lt;25 years of age and women ≥25 years of age who are at risk at least annually for CT and GC</td>
<td>Test for CT and GC</td>
<td>Test for CT, GC, <em>Trichomonas vaginalis</em> (TV) and bacterial vaginosis (BV)</td>
<td>Test for TV, BV and Candida</td>
<td>Test for CT, GC, syphilis and herpes simplex virus</td>
<td>Test for CT and GC</td>
<td>Test for CT and GC</td>
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<tr>
<td>Screen pregnant women &lt;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 &lt;25 years of age and/or at high risk</td>
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<tr>
<td>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</td>
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<tr>
<th>Tier 2: Approaches to consider when STI diagnostic test kits are limited</th>
<th>Asymptomatic individuals</th>
<th>Men with symptomatic urethritis syndrome</th>
<th>Women with cervicitis syndrome</th>
<th>Women with vaginits syndrome</th>
<th>Proctitis syndrome</th>
<th>Complicated STD syndromes (PID)</th>
<th>Contacts to GC and/or CT</th>
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<tbody>
<tr>
<td>Prioritize women &lt;25 years of age; pregnant women &lt;25 years of age; women ≥25 years of age at risk**; pregnant women ≥25 years of age at risk*** and MSM</td>
<td>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</td>
<td>Vaginal or endocervical testing for CT and GC; Wet prep for BV and TV testing**</td>
<td>Perform wet mount for TV, BV and Candida</td>
<td>Rectal testing for CT and GC</td>
<td>Vaginal or endocervical testing for CT and GC</td>
<td>Treat for appropriate organism</td>
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<tr>
<td>Vaginal testing (women), rectal and pharyngeal trunk testing (MSM) for CT and GC</td>
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<td>Reserve urine-based testing for persistent urethritis</td>
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<tr>
<th>Tier 3: Approaches to take when STI diagnostic tests kits are severely limited or not available</th>
<th>Asymptomatic individuals</th>
<th>Men with symptomatic urethritis syndrome</th>
<th>Women with cervicitis syndrome</th>
<th>Women with vaginits syndrome</th>
<th>Proctitis syndrome</th>
<th>Complicated STD syndromes (PID)</th>
<th>Contacts to GC and/or CT</th>
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<tbody>
<tr>
<td>No screening</td>
<td>See guidance in DCLs regarding syndromic management</td>
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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
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.

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<th>PrEP Drug Interactions</th>
<th>Truvada® (FTC/TDF)</th>
<th>Descovy® (FTC/TAF)</th>
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| **Drugs affecting renal function**<sup>*</sup>  
Ex: acyclovir, adeovir 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](#). | 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-gp inhibitors**<sup>*</sup>  
Ex: Clarithromycin, verapamil, ketoconazole, itraconazole | Increases TDF exposure, but okay to use if monitoring renal function. | Increases TAF exposure, but okay to use if monitoring renal function. |
| **Strong P-gp inducers**<sup>*</sup>  
Ex: Rifampin, rifapentine, oxcarbazepine, carbamazepine, phenobarbital, phenytoin, St. John’s Wort | Okay to use. Only a small decrease in TDF is expected because the dose of TDF outweighs effect of efflux by P-gp. | **DO NOT USE**. Decreases TAF exposure. The dose of TAF is not enough to overpower P-gp inducers. |

*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.

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?

- Design and development
- Manufacturing & safety studies
- Human studies

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

[NIH National Institute of Allergy and Infectious Diseases](www.niaid.nih.gov)  [facebook.com/niaid.nih](facebook.com/niaid.nih)  [@NIAIDNews](@NIAIDNews)