PrEP Updates Newsletter

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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 200mg/tenofovir disoproxil fumarate 300mg, TDF-FTC, Truvada®
 - o Emtricitabine 200 mg/tenofovir alafenamide 25 mg, TAF-FTC, Descovy®
- <u>PrEP is a Grade A recommendation by the USPSTF</u> for at-risk populations for HIV prevention
- PrEP and associated medical costs can be minimal, even for uninsured patients, in Colorado
 - o Colorado PHIP Program can cover PrEP medical visits & labs, STI testing/treatment
 - o 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
 - o Includes access for uninsured patients through the Colorado PHIP Program
 - o For more information call PrEP coordinator Amanda Ahumada at 303-724-8245

PrEP in the time of COVID-19

- The CDC Division of HIV/AIDS Prevention sent a Dear Colleague Letter on May 15th 2020 with advice for PrEP providers in the time of COVID-19:
 - 1. Reducing the number of new HIV infections remains a public health priority, and providing PrEP care is an essential health service. Clinicians should continue to ensure the availability of PrEP for patients newly initiating PrEP and patients continuing PrEP use.
 - 2. Quarterly HIV testing should be continued for patient safety. Lab-only visits for assessment of HIV infection and other indicated tests for the provision of PrEP are preferred. When these are not available or feasible, CDC recommends considering two additional options.
 - The first option is a home specimen collection kit for HIV and sexually transmitted infection (STI) tests, which is covered by most insurance plans and can be ordered by clinicians. Specimen kits are mailed to the patient's home and contain supplies to collect blood from a fingerstick or other appropriate method (e.g. self-collected swabs and urine). The kit is then mailed back to the lab with test results returned to the clinician who acts on results accordingly. This laboratory-conducted test is sensitive enough to detect recent HIV infection.
 - Note: The IDGP has access to free home test kits. <u>Contact us for more information</u>
 - The second option is self-testing via an oral swab-based test. Although this type of <u>HIV self-test</u> is usually not recommended for PrEP patients due to its lower sensitivity in detecting recent HIV infection during PrEP use, clinicians could consider use of these tests when other options are not available.

- 3. When HIV-negative status is confirmed, consider providing a prescription for a 90-day supply of PrEP medication (rather than a 30-day supply with two refills) to minimize trips to the pharmacy and to facilitate PrEP adherence. Several programs are available to help provide affordable PrEP medication including Ready, Set, PrEP, a nationwide program that makes PrEP medications available at no cost to individuals who qualify and lack prescription drug coverage; state drug assistance programs; and Gilead's Medication Assistance Program (MAP), which assists eligible HIV-negative adults in the United States who require assistance paying for PrEP.
- 4. If a PrEP clinic is considering closing or suspending services temporarily, health care providers should establish referral relationships with other clinics, telemedicine services, or pharmacies so that clients may remain engaged in PrEP care.

Sexually Transmitted Infections (STIs) in the time of COVID-19

- Did you know that a new STI diagnosis is an HIV risk factor and therefore an indication for PrEP?
- STIs are on the rise nationally and in Colorado, see this recent advisory by CDPHE:



Advancing Colorado's health and protecting the places we live, learn, work and play

HEALTH ALERT NETWORK BROADCAST

MESSAGE ID: 01162020 10:45

FROM: CO-CDPHE

SUBJECT: HAN Advisory - Sharp rise in STIs in Colorado continues, includes congenital syphilis

RECIPIENTS: Local Public Health Agencies / EDs / ID Physicians

HEALTH ADVISORY | Sharp rise in STIs in Colorado continues, includes congenital syphilis

Jan. 16, 2020

Health care providers: Please distribute widely in your office

Key points

- Sexually transmitted infections (STIs) are increasing in the United States and Colorado. There has
 been a 32.5% increase in the rate of syphilis (all stages), a 6.4% increase in the rate of chlamydia;
 and a 3.3% increase in the rate of gonorrhea in Colorado from 2017 to 2018. Increases in STIs are
 also increasing at the national level.
- The increase in syphilis has contributed to an increase in congenital syphilis (CS) and ocular syphilis cases in Colorado.
- Syphilis, gonorrhea, and chlamydia are bacterial infections that can increase the risk of HIV
 acquisition and transmission. CDPHE's preliminary data indicates that dual diagnoses with STI and
 HIV are increasing, especially for syphilis.
- It is critical that health care providers offer comprehensive screening for STIs and HIV to all
 patients at risk (see below).
- The CDC and several state health departments have patient information on STIs and sexual health in the time of COVID, focusing on empiric therapies when in-person visits may be limited or not available
 - https://www1.nyc.gov/assets/doh/downloads/pdf/imm/ept-partner-guidance.pdf
 - o https://www.cdc.gov/coronavirus/2019-ncov/hcp/non-covid-19-client-interaction.html

Table 1. Therapeutic options to consider for symptomatic patients and their partners when in person clinical evaluation is not feasible:

Syndrome	<u>Preferred Treatments</u> In clinic, or other location where	Alternative Treatments When only oral medications	Follow-up
	injections can be given*	are available ^a	
Male urethritis syndrome	Ceftriaxone 250mg intramuscular (IM) in a single dose PLUS Azithromycin I gorally in a single dose (If azithromycin is not available and patient is not pregnant, then doxycycline 100 mg orally twice a day for 7 days is recommended).	Cefixime 800 mg orally in a single dose PLUS Azithromycin 1g orally in a single dose (If azithromycin is not available and the patient is not pregnant, doxycycline 100 mg orally twice a day for 7 days is recommended). OR	For alternative oral regimens, patients should be counseled that if their symptoms do not improve or resolve within 5-7 days, they should follow-up with the clinic or a medical provider.
	If cephalosporin allergy is reported, gentamicin 240 mg IM in a single dose PLUS azithromycin 2 g orally in single dose is recommended.	Cefpodoxime 400 mg orally q12 hours x 2 doses PLUS Azithromycin lg orally in a single dose (If azithromycin is not available and the patient is not pregnant, doxycycline 100 mg orally twice a day for 7 days is recommended). If oral cephalosporin is not available or cephalosporin allergy is reported, azithromycin 2g orally in a single dose.	Patients should be counseled to be tested for STIs once clinical care is resumed in the jurisdiction. Health departments should make an effort to remind clients who have been referred for oral treatment to return for comprehensive testing and screening and link them to services at that time.
Genital ulcer disease (GUD) Suspected primary or secondary syphilis**	Benzathine penicillin G, 2.4 million units IM in a single dose.	Males and non-pregnant females: Doxycycline 100 mg orally twice a day for 14 days. Pregnant: Benzathine penicillin G, 2.4 million units IM in a single dose.	All patients receiving regimens other than Benzathine penicillin for syphilis treatment should have repeat serologic testing performed 3 months post-treatment.
Vaginal discharge syndrome in women without lower abdominal pain, dyspareunia or other signs concerning for pelvic inflammatory disease (PID)	Treatment guided by examination and laboratory results.	Discharge suggestive of bacterial vaginosis or trichomoniasis (frothy, odor): Metronidazole 500 mg orally twice a day for 7 days. Discharge cottage cheese-like with genital itching: Therapy directed at candida.	
Proctitis syndrome#	Ceftriaxone 250mg IM in a single dose PLUS doxycycline 100 mg orally twice a day for 7 days. If doxycycline not available or the patient is pregnant, azithromycin 1g orally in single dose recommended.	Cefixime 800 mg orally in a single dose PLUS doxycycline 100 mg orally bid for 7 days (if doxycycline not available or the patient is pregnant, azithromycin 1g orally in single dose recommended). OR Cefpodoxime 400 mg orally q12 hours x 2 doses PLUS doxycycline 100 mg orally bid for 7 days (if doxycycline not available or the patient is pregnant, azithromycin 1g orally in single dose recommended).	

*When possible, clinics should make arrangements with local pharmacies or other clinics that are still open and can give injections

Source: https://californiaptc.com/wp-content/uploads/2020/04/InterimSTDTxGuidelines-CAPTC.pdf

PrEP On-Demand or 2-1-1

- Intermittent PrEP, also known as On-Demand PrEP or 2-1-1, is an off-label, alternative use of TDF-FTC (Truvada) before/after sexual intercourse for men who have sex with men (MSM).
- Intermittent PrEP is endorsed by the World Health Organization (WHO) and the International Antiviral Society-USA (IAS-USA) for MSM with infrequent sexual exposures.^{1,2}

IAS & WHO Recommended populations for intermittent PrEP^{1,2}

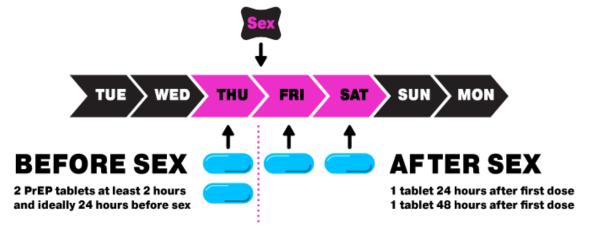
- Use is recommended for individuals who have anal sex infrequently (<twice a week), who can plan ahead and who find an intermittent regimen more convenient.
- Use is not recommended for other groups including individuals having vaginal sex, cisgender women, transgender women, transgender men, men who have sex with women, and individuals on estradiol or testosterone therapy, due to lack of data.
- o Individuals with hepatitis B infection should not take intermittent PrEP.

^{*}Alternative regimens should be considered when recommended treatments from the 2015 CDC STD Treatment Guidelines are not available
**All pregnant women with syphilis must receive Benzathine penicillin G. If clinical signs of neurosyphilis present (e.g. cranial nerve

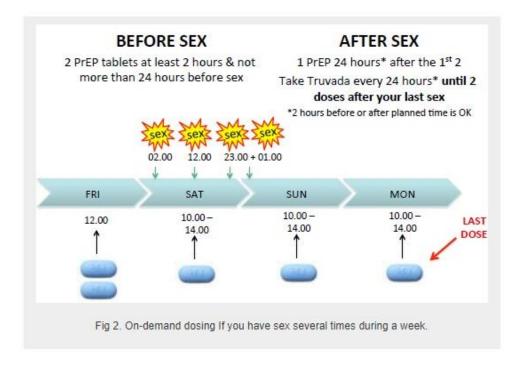
dysfunction, auditory or ophthalmic abnormalities, meningitis, stroke, acute or chronic altered mental status, loss of vibration sense), further evaluation is warranted

Prescription Parameters and Monitoring^{1,2}

- Intermittent PrEP should be taken as 2 pills before sexual activity and 2 pills after sexual activity, as per the diagram below
 - o If ongoing sex occurs, continue daily PrEP until 48 hours after last sex.
 - If no PrEP in the last 7 days, you should start over with two pills before next sex.
- Prescribe 30 pills with 2 refills or 90 pills with no refills, just as you would for daily PrEP.
 - o Individuals should not use intermittent PrEP as a way to conserve their medication and should not share the prescription with others.
- Every 3-month HIV testing and following up is still recommended just as with daily PrEP.



If sexual activity continues, take 1 PrEP tablet every 24 hours until 48 hours after last sex. (Adapted from i-Base.info.)



References

- 1. https://www.iasusa.org/wp-content/uploads/guidelines/arv/arv 2018.pdf
- 2. https://www.who.int/hiv/pub/prep/211/en/
- 3. http://i-base.info/guides/prep/real-life-examples-for-on-demand-dosing

PrEP Smart Set for EPIC

Did you know that we have a new tool to simplify orders for PrEP for ambulatory medicine at Uchealth?

- The **PrEP SmartSet** below contains the diagnosis codes, labs, medication options and follow up suggested for PrEP, based on CDC guidelines and CDPHE PHIP program recommendations.
- You can find this by searching in a patient encounter under the SmartSets tab for PrEP, right click to add to your favorites and then open to add orders to your encounter.

PrEP ♣ Personalize ▼ <	
▼ Diagnosis	
▼ Diagnosis code	
Exposure to HIV [Z20.6]	
On pre-exposure prophylaxis for HIV [Z79.89	99]
▼ Medications	
▼ Medications	
emtricitabine-tenofovir (TRUVADA) 200-300 Disp-90 tablet, R-0	mg per tablet take one tab daily, quantity 90, refills 0
emtricitabine-tenofovir (TRUVADA) 200-300 Disp-30 tablet, R-0	mg per tablet take one tab daily, quantity 30, refills 0
emtricit-tenofovir alafen (DESCOVY) 200-25 Disp-90 tablet, R-0	mg per tablet take one tab daily, quantity 90, refills 0
emtricit-tenofovir alafen (DESCOVY) 200-25 Disp-30 tablet, R-0	mg per tablet , take one tab daily, quantity 30, refills 0
▼ Labs - baseline visit	
▼ Labs - baseline visit	
Basic Metabolic Panel	
Routine	Pregnancy Test Urine
Chlamydia/GC Gen Probe Urine Routine	Routine
Chlamydia/GC Gen Probe Throat	☐ UA Complete Urinalysis (No Culture Reflex) ☐ (1) Routine
Chlamydia/GC Gen Probe Rectal	Labs - follow up visit
Routine	▼ Labs - follow up visit (recommended every 3 months)
☐ Hepatic Function Panel ■ Routine	Basic Metabolic Panel Routine
☐ Hepatitis A Antibody ■ Routine	☐ HIV 1/2 Antibody/Antigen Screen ■ Routine
☐ Hepatitis B Surface Antibody ■ Routine	Pregnancy Test Urine Routine
☐ Hepatitis B Surface Antigen ■ Routine	Chlamydia/GC Gen Probe Rectal Routine
☐ Hepatitis C Virus Antibody ■ Routine	Chlamydia/GC Gen Probe Throat Routine
☐ HIV 1/2 Antibody/Antigen Screen ■ Routine	Chlamydia/GC Gen Probe Urine Routine
☐ Treponema Antibodies ☐ Routine	Treponema Antibodies Routine