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

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Available PrEP Medications, Financial Assistance Programs & EPIC tools  
- PrEP is Pre-Exposure Prophylaxis, medication to prevent HIV acquisition before an exposure  
- There are three FDA approved medications for PrEP with Grade IA recommendation by the CDC:  
  - Daily oral PrEP  
    - **Emtricitabine 200mg/tenofovir disoproxil fumarate 300mg, F/TDF, Truvada®**  
      - FDA approved for all genders at risk of sexually acquired HIV and also for HIV risk related to use of injection drugs  
      - Available as a generic medication with no copay under most plans  
    - **Emtricitabine 200 mg/tenofovir alafenamide 25 mg, F/TAF, Descovy®**  
      - FDA approved for cisgender men & transgender women, not approved for cisgender women/vaginal sex/injection drug use  
      - Brand only, copay assistance cards available  
  - Injectable PrEP  
    - **Cabotegravir 600 mg, Apretude®,** a long acting IM injection every 2 months  
      - FDA approved for all genders at risk of sexually acquired HIV  
      - Dosing: 600 mg IM, repeat in one month then every 2 months  
      - Brand only, challenging to obtain regarding insurance coverage and availability, must be given in a clinic setting  
  - **PrEP is a Grade A recommendation** by the USPSTF for at-risk populations for HIV prevention  
    - PrEP is required to be covered as a preventative care under most insurance plans  
  - PrEP and associated medical costs can be covered, even for uninsured patients, in Colorado  
    - **Colorado PHP Program** can cover medical visits, labs, STI testing  
    - **Gilead Advancing Access Program** & **Viiv Patient Assistance Program** for medications  
  - **IDGP TelePrEP Program:** virtual clinic visits with free home testing kits for Colorado residents  
    - If interested contact our IDGP PrEP coordinator at 303-724-8245  
  - **UCHealth EPIC tools:** Did you know we have PrEP SmartSets w/diagnosis codes, medications, labs per CDC guidelines, sexual health vaccines and follow up?  
    - Find the SmartSet icon directly under the Plan tab in a visit encounter or under the Triage tab in telephone encounter (note this is not located in the usual orders tab)  
    - Search “Oral or Injectable PrEP for HIV Prevention”, right click to favorite
DoxyPEP: Review of the Data

- As some individuals and clinicians may be using off-label use of doxycycline as bacterial sexually transmitted infection (STI) post-exposure prophylaxis, known as DoxyPEP, here is CDC guidance:
  - Data supports off-label use in cisgender men who have sex with men (MSM) and transgender women (TGW) with a recent STI, not effective in cisgender women
  - Doxycycline 200 mg x 1 within 24-72 hours of condomless sex was the regimen used in this study, do not use other antibiotics for PEP
  - Providers should counsel patients on the STI prevention benefits of doxy-PEP as well as potential adverse side effects: phototoxicity, GI upset, rare esophageal ulceration
  - Providers should continue to screen and treat for bacterial STIs in accordance with CDC’s STI Treatment Guidelines and CDC’s PrEP for the Prevention of HIV guidelines

- Data supporting use: DoxyPEP Study: randomized, open label trial by Luetkemeyer et al (NEJM)
  - DoxyPEP in cisgender MSM + TGW in Seattle and San Francisco with a recent STI → found decreased incidence of gonorrhea, chlamydia & syphilis by two-thirds
    - **Dosing**: Doxy 200 mg within 24 hours and no later than 72 hours after any condomless sex (anogenital, vaginal or oral); no more than one dose in 24 hours
    - **Study population**: persons on HIV PrEP and persons living with HIV (PLWH) with an STI in the past year and report of condomless sex with one or more partners
    - **Methods**: randomized 2:1 to receive doxy-PEP or no PEP (standard-care) and followed with quarterly visits for STI screening
    - **Results**: Primary endpoint → incidence of at least 1 STI each quarter
      - Reduction of incident STIs was 65% overall per quarter
        - STIs per quarter in those on DoxyPEP vs. no PEP, respectively:
          - 10.7% vs 31.9% in PrEP cohort, NNT = 4.7
          - 11.8% vs 30.5% in PLWH cohort, NNT = 5.3
      - Most common STI: gonorrhea, higher proportion of incident gonorrhea with tetracycline resistance in the doxy groups vs control groups
        - Suggests potential decreased protection against circulating tetracycline-resistant N. gonorrhoeae isolates
      - Microbiome impact: no significant difference in doxycycline-resistant S. aureus isolated in doxy vs control groups (5% and 4%, respectively)
        - Unclear what long-term impacts may be, warrants further study

- Data against use: no benefit of Doxy-PEP in cisgender women in Kenya in randomized OL trial
  - Population: 18-30 year old cisgender women on HIV PrEP, doxy-PEP vs standard of care
  - Primary outcome
    - Incidence of gonorrhea, C trachomatis or early syphilis quarterly for 1 year
    - 17.9% prevalence of STIs with C trachomatis being the most common

- References:
Increase in Extensively Drug-Resistant (XDR) Shigellosis in the United States & Colorado

- **What?**
  - Shigellosis is an acute enteric infection that is an important cause of domestically acquired and travel-associated bacterial diarrhea in the United States.
  - Shigellosis usually causes inflammatory diarrhea that can be bloody and may also lead to fever, abdominal cramping, and tenesmus.

- **How?**
  - Shigella can be transmitted by the fecal-oral route, directly through person-to-person contact, and indirectly through contaminated food, water, and other routes. Outbreaks tend to occur among people in close-contact settings.
  - Shigella can also be transmitted sexually related to fecal-oral spread with certain sexual practices, as can other pathogens that cause infectious diarrhea.

- **Who?**
  - Consider shigellosis in the differential diagnosis of acute diarrhea, especially for patients at higher risk for Shigella infection:
    - Young children
    - MSM
    - People experiencing homelessness
    - International travelers
    - Immunocompromised persons
    - People living with HIV

- **Diagnosis and treatment:**
  - Diagnosis is by Stool GI PCR (UCHealth lab) or stool culture.
  - Infections are generally self-limiting; however, antimicrobial treatment may be indicated to prevent complications or shorten the duration of illness.
  - In 2022, about 5% of Shigella infections reported to CDC were caused by XDR strains (resistant to azithromycin, ciprofloxacin, ceftriaxone, TMP-SMX, and ampicillin) compared with 0% in 2015—prompting a CDC HAN alert in February of 2023.
  - Colorado has seen increasing rates of Shigella over the past five years, with 373 cases (32 XDR cases) reported in 2022. Shigella is a reportable condition in Colorado and all culture or PCR positive cases of Shigella must be reported to CDPHE.

- **If shigellosis is suspected:**
  - Ask about relevant exposures, sexual activity, housing status, and international travel.
    - If suspicious for sexually acquired shigella, screen for STIs & HIV.
  - Most patients recover from shigellosis without antimicrobial treatment, those who do not improve without treatment, are immunocompromised, or have severe disease warrant treatment with antibiotics.
  - Obtain a stool culture and request anti-microbial susceptibility testing for patients who will require antimicrobial treatment, refer suspected XDR cases to Infectious Diseases.
**Patient Counseling for Shigellosis**
- Stay home from school or from healthcare, food service, or childcare jobs while sick or until the health department says it’s safe to return.
- During diarrhea and for 2 weeks after it ends:
  - Abstain from sex (anal, oral, penile, or vaginal)
  - Practice meticulous hand hygiene
  - Do not prepare food for others, if possible
  - **Stay out of recreational water**, including swimming pools, hot tubs, water playgrounds, oceans, lakes, and rivers
  - Closely follow safer sex practices for at least 2 weeks after resuming sex to prevent the spread of *Shigella* bacteria that may remain in stool

*Source: CDC HAN February 2023*

**Mycoplasma genitalium: Testing & Treatment Updates**
- **CDC STI 2021 Guidelines** address recommendations for testing and treatment of an organism that can be sexually transmitted and is often multi-drug resistant, *Mycoplasma genitalium*.
- **Symptoms:** predominantly causes infection in the genitourinary tract and can cause persistent or recurrent non-gonococcal urethritis (NGU), cervicitis and pelvic inflammatory disease (PID).
  - Consider testing in patients with persistent or recurrent STI or vaginitis symptoms who have had a negative work up or treatment for typical pathogens.
    - Drug resistance is increasingly with *M. genitalium* and macrolide-resistance testing is recommended if available (a send out lab).
- **Diagnosis:** FDA-cleared Nucleic Acid Amplification Tests (NAATs) are recommended for detection of *M. genitalium*, as it does not usually grow in routine cultures.
  - UHealth lab now offers this test in house with a faster turnaround time of 24-72 hours, than our prior send out test which could take a week to return!
    - **Name of lab:** Mycoplasma Genitalium Amplification (aka mgenamp)
    - **Accepted specimens:**
      - **Urine:** HOLOGIC Aptima® Urine Specimen Collection Kit.
        - Also, acceptable: 2 mL of urine in a Clear Top (non-additive, sterile container) received in lab within 24 hours of collection.
      - **Genital:** HOLOGIC Aptima® Unisex Swab Specimen Collection Kit -or- Aptima® Multitest Swab Collection Kit.
        - For persons with a vagina, vaginal swab preferred to urine.
- **Treatment:** *Treatment requires dual therapy in sequence due to drug resistance* 
  - **CDC Guidelines** are based on whether sensitivity testing is done/available (available only as a send out, therefore recommend the first treatment approach below):
    - **If macrolide resistant or sensitivity testing not available:** Doxycycline 100 mg orally 2 times/day for 7 days followed by moxifloxacin 400 mg orally once daily for 7 days.
    - **If sensitivity testing available and sensitive to macrolides:** Doxycycline 100 mg orally 2 times/day for 7 days, followed by azithromycin 1 g orally initial dose, followed by 500 mg orally once daily for 3 additional days (2.5 g total).