National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Division of STD Prevention



STD Treatment Options During COVID-19

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Outline

- Introduction
- Review content of Dear Colleague Letter
- Drug shortage update
- Lessons from the field
- Q and A

Dear Colleague Letter released April 6, 2020

- Guidance provided in response to questions from the field related to disrupted clinical care provision due to COVID-19
- Goal: Offer flexible, pragmatic harm-reduction approach
- <u>Challenge:</u> Heterogeneity of COVID-19 impact on individual jurisdictions, varying levels of resources available at local level
- Assumption: In-person care not achievable or scaled back due to public health measures necessitated for COVID-19 mitigation

Priorities

- Prioritize visits at clinics that remain open with reduced staffing for patients who:
 - Have STD symptoms
 - Report STD contact
 - Are at risk for complications such as:
 - Individuals with vaginal discharge and abdominal pain
 - Pregnant persons with syphilis and their partners
 - Individuals with symptoms concerning for neurosyphilis

 Routine screening visits should be deferred until clinical schedules allow increased number of patient visits

Strategies

- Implement phone or telemedicine-based approaches, including syndromic management of:
 - Male urethritis
 - Suspected primary or secondary syphilis
 - Vaginal discharge
 - Proctitis
- A triage protocol that includes identification and referral for additional evaluation individuals at risk for complications is essential.

Partnerships and Innovation

- If an STD program is considering closing clinics, STD programs should try to establish relationships with other clinics and/or pharmacies that can provide preferred injectable treatments
 - Ceftriaxone
 - Bicillin

Symptomatic patients and their known contacts could be referred to these sites for syndromic treatment

Syndrome	Preferred Treatment In clinic, or other location where injections can be given*	Alternative Treatment When only oral medications are available ^{&}
Male urethritis syndrome	Ceftriaxone 250mg intramuscular (IM) in a single dose PLUS Azithromycin 1g orally 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). If cephalosporin allergy is reported, gentamicin 240 mg IM in a single dose PLUS azithromycin 2 g orally in single dose is recommended.	Azithromycin 1g orally in a single dose (If azithromycin is not available and the patient is not
arrangements with local pha	*When possible, clinics should make arrangements with local pharmacies or other clinics that are still open and can give injections.	If oral cephalosporin is not available or cephalosporin allergy is reported, azithromycin 2g orally in a single dose. &Alternative regimens should be considered when recommendations treatments from CDC 2015 Treatment Guidelines are not available

Syndrome	Preferred Treatment In clinic, or other location where injections can be given*	Alternative Treatment When only oral medications are available &
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.
++ All pregnant women with syphilis must receive Benzathine penicillin G.		Pregnant: Benzathine penicillin G, 2.4 million units IM in a single dose.
^ 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	*When possible, clinics should make arrangements with local pharmacies or other clinics that are still open and can give injections	^{&} Alternative regimens should be considered when recommendations treatments from CDC 2015 Treatment Guidelines are not available

Syndrome	Preferred Treatment In clinic, or other location where injections can be given*	Alternative Treatment When only oral medications are available ^{&}
Vaginal discharge syndrome in women without lower abdominal pain, dyspareunia or other signs concerning for pelvic inflammatory disease (PID)	Treatment guided by examination and lab 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.
	*When possible, clinics should make arrangements with local pharmacies or other clinics that are still open and can give injections.	*Alternative regimens should be considered when recommendations treatments from CDC 2015 Treatment Guidelines are not available.

Syndrome	Preferred Treatment In clinic, or other location where injections can be given*	Alternative Treatment When only oral medications are available ^a
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 q 12 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).
#Consider adding therapy for herpes simplex virus if pain present	*When possible, clinics should make arrangements with local pharmacies or other clinics that are still open and can give injections	^{&} Alternative regimens should be considered when recommendations treatments from CDC 2015 Treatment Guidelines are not available

Follow-up

- For alternative oral regimens, patients should be counseled that if their symptoms do not improve or resolve within 5-7 days, they should followup with the clinic or a medical provider
- 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
- All patients receiving regimens other than Benzathine penicillin G for syphilis treatment should have repeat serologic testing performed 3 months post-treatment

Additional Guidance on Expedited Partner Therapy (EPT)

- EPT is an important harm reduction strategy in STD control
 - Reserved for situations where a partner would not otherwise receive treatment
- EPT legal restrictions vary by state
- EPT has been studied and shown to be safe and effective for gonorrhea and chlamydia
- CDC does not currently recommend the use of EPT for syphilis
 - No data exists on EPT for syphilis
 - Patients need a healthcare evaluation to determine stage of syphilis (e.g., early versus late) and to rule out complications (i.e., neurologic, ocular or otic symptoms), and pregnancy
 - Laboratory tests to confirm syphilis diagnosis and to follow response to care are essential and might not be available if EPT is employed

Drug Shortages

Roxanne Barrow, MD, MPH

STD Drug Availability

- DSTDP continues to monitor the situation and work closely with the FDA
- As of 5/7/2020, FDA reports shortages of azithromycin
- No shortages of key STD medications including
 - ceftriaxone, cefixime, cefpodoxime, doxycycline, gentamicin, penicillin, metronidazole
- Local distribution issues may impact availability of medications
- Notify health department regarding STD medication shortages

STD Drug Availability (as of 5/7/2020)

Medication	FDA Drug Shortage	Update
Azithromycin	Yes (as of 4/14/2020)	 Several manufacturers Product available based on manufacturer See FDA drug shortage website for current availability
Benzathine penicillin	No	One manufacturer: PfizerNo supply issues
Cefixime	No	 Two manufacturers of tablets: Ascend and Lupin Ascend: product available Increased production to meet market demand
Cefpodoxime	No	 Two main manufacturers: Sandoz and Aurobindo Increased demand No supply issues

STD Drug Availability (as of 5/7/2020)

Medication	FDA Drug Shortage	Update
Ceftriaxone	No	Several manufacturersTight supply but no supply issues
Doxycycline	No	Several manufacturersNo supply issues
Gentamicin	No	 Two main manufacturers: Pfizer and Fresenius Kabi ASHP drug shortage website as of 3/30 Not currently on the FDA drug shortage website-enough product is in the supply chain Pfizer: release expected in May Fresenius Kabi: release expected in June

STD Drug Availability (as of 5/7/2020)

Medication	FDA Drug Shortage	Update
Metronidazole	No	Several manufacturersTight supply but no supply issues
Erythromycin (0.5%) ophthalmic ointment	Yes (as of 3/5/2019)	 Three manufacturers Product availability based on manufacturer See FDA drug shortage website for current availability
Lidocaine	Yes (as of 2/22/2012)	 Several manufacturers Product availability based on manufacturer See FDA drug shortage website for current availability

Experiences from the frontline

Experience from the frontlines

Dr. Hilary Reno, MD, PhD Washington University in St. Louis PTC

Assistant Professor of Medicine, Infectious Diseases, Washington University in St. Louis
Medical Consultant, CDC, Division of STD Prevention
Medical Director, St. Louis County Sexual Health Clinic
Director, St. Louis STI Regional Response Coalition (www.stlstirr.org)
Associate Medical Director, St. Louis STD/ HIV Prevention Training Center

St. Louis County Sexual Health Clinic, MO

*Metropolitan area of 2.8 million, some public transport, racial disparities, high uninsured rate

*Clinic demographics: 91% African-American, 90% uninsured, 60% men, 5-10% MSM, PrEP clinic

March 17, first COVID19 case in St. Louis

- 1. Social Distancing:
- --clinic space
- --volume
- 2. Telemedicine available
- --how and when to use
- 3. Develop priorities for future

March 24, Stay At Home orders

- 1. Appointments only
- --filling 2-3 days ahead
- 2. Masks/ PPE concerns
- -- lack of homemade masks
- 3. Regional Capacity
- --Mapping regional test/ treat

*Lifting of Stay At Home

- 1. Increasing capacity
- --Increase visits
- --when to decrease screening visits?
- --PrEP clinic (20% of all PrEP scripts in 6 weeks)
- 2. Public facing regional dashboard of services, with frequent updates.

Experiences from the frontlines

Dr. Jason Zucker, MD Columbia University in NYC PTC

Infectious Disease Specialist

Instructor in Medicine and Pediatrics at Columbia University Irving Medical Center

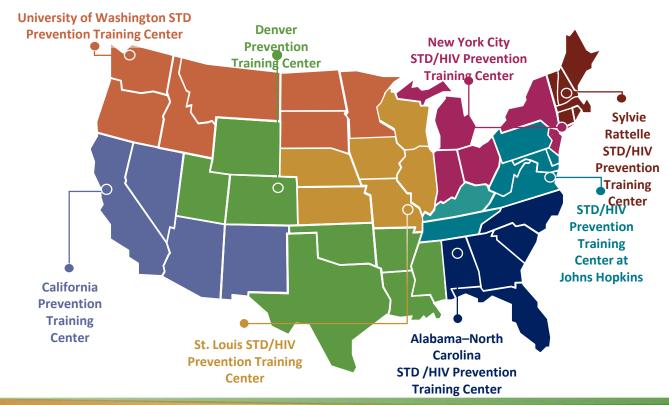
Core faculty at Columbia University PTC

Questions?

Common questions encountered to date:

- What is the cefixime dose for GC EPT?
 - Cefixime 800 mg PLUS azithromycin or doxycycline
- Is TOC recommended for alternative regimens for GC (particularly oral)?
 - Yes, TOC is recommended for alternative regimens for oral GC
- Where can I find resources for innovative approaches?
 - https://www.ncsddc.org/covid-command-center-std-clinic-resources/
 - https://www.ncsddc.org/resource/covid-command-center-for-stdprograms/

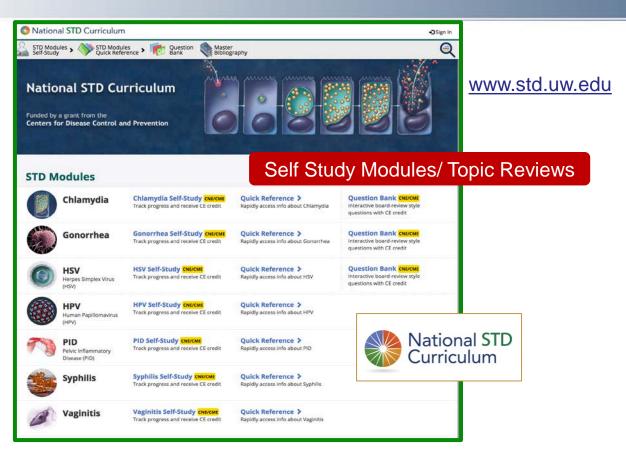




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STD Clinical Consultation Network

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Additional Questions?

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For more information, contact CDC 1-800-CDC-INFO (232-4636) TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

