Managing Syphilis Amidst Penicillin Shortage

Learning Community, September 26th

Welcome! Please introduce yourself in the chat ©



COLUMBIA VAGELOS COLLEGE OF PHYSICIANS AND SURGEON

Welcome and happy fall!

• Please introduce yourself in the chat!

- We're happy to have attendees here from the following clinics:
 - Bell Flower Clinic, Indianapolis, Indiana
 - Litoral Clinic, Migrant Health Center, Mayagüez, Puerto Rico
 - Mary Eliza Mahoney Health Center, Newark, New Jersey
 - Morrisania Clinic, Health & Hospitals, Bronx, New York
 - NYC Department of Health, NYC, New York
 - Take Care Down There Clinic, Columbus Public Health, Columbus, Ohio



Group Agreements

- Keep cameras on, especially when talking
- All participants contribute to the discussion
- We're here to learn together
- Confidentiality: any patient information shared remains private



Clinic Prompt

Has your clinic explored its current penicillin stock?

How your clinic managing syphilis amidst this shortage? What changes, if any, have been made?



COLUMBIA VAGELOS COLLEGE OF PHYSICIANS AND SURGEON

Managing Syphilis: Providing Clinical Care in the Era of Bicillin-LA Shortages

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Twitter: @Jason10033





• None



Objectives

- 1. Recognize the importance of screening for syphilis
- 2. Accurately classify syphilis by stage
- 3. Summarize recommended and not recommended treatment options
- 4. Develop plans for management during the Bicillin-LA shortage for your clinic
- 5. Understand appropriate syphilis follow-up



Sexually Transmitted Diseases



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Centers for Disease Control and Prevention. Sexually Transmitted Disease Surveillance 2019. Atlanta: U.S. Department of Health and Human Services; 2021.



Sexually Transmitted Diseases



Centers for Disease Control and Prevention. Sexually Transmitted Disease Surveillance 2019. Atlanta: U.S. Department of Health and Human Services; 2021.



Sexually Transmitted Diseases



Centers for Disease Control and Prevention. Sexually Transmitted Disease Surveillance 2019. Atlanta: U.S. Department of Health and Human Services; 2021.



Syphilis is Rising





STOPPREVENTION TRAINING CENTER

https://www.cdc.gov/stopsyphilis/exec.htm

https://www.cdc.gov/std/statistics/2021/default.htm

Syphilis is Rising





STP PREVENTION TRAINING CENTER

https://www.cdc.gov/stopsyphilis/exec.htm

https://www.cdc.gov/std/statistics/2021/default.htm

Syphilis is Rising





Screening for Syphilis

Population	Recommendations
len who have sex with men	At least annually if sexually active, and every 3-6 months if at increase stiches
Transgender and Gender Diverse People	Consider screening at least annually based on reported
Patients taking PrEP	At initiation and every 3-6 months if at increases answitted.
Persons living with HIV	At diagnosis and at least annually Transvery 3-6 months if at increased risk
Non-pregnant Women Cis-gender) and Non-MSM Men	At least annually if sexually active, and every 3-6 months if at increase the second s
Pregnant Women	sounter plus third trimester and at delivery if high risk or in endemic area



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Syphilis – Traditional Algorithm





Syphilis – Reverse Algorithm



New York City Department of Health and Mental Hygiene, and the New York City STD Prevention Training Center. The Diagnosis and Management of Syphilis: An Update and Review. March 2019. A PDF version is available at www.nycptc.org.



Syphilis – Interpreting Titers

1:2048 1:1024 1:512 1:256 1:128 1:64 1:32 1:16 1:8 1:4 1:2 1:1 **Nonreactive**





Syphilis – Interpreting Titers



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https://www.nycptc.org/x/Syphilis_Monograph_2019_NYC_PTC_NYC_DOHMH.pdf



New York City Department of Health and Mental Hygiene, and the New York City STD Prevention Training Center. The Diagnosis and Management of Syphilis: An Update and Review. March 2019. A PDF version is available at www.nycptc.org.





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New York City Department of Health and Mental Hygiene, and the New York City STD Prevention Training Center. The Diagnosis and Management of Syphilis: An Update and Review. March 2019. A PDF version is available at www.nycptc.org.





New York City Department of Health and Mental Hygiene, and the New York City STD Prevention Training Center. The Diagnosis and Management of Syphilis: An Update and Review. March 2019. A PDF version is available at www.nycptc.org.



Syphilis – Primary

• Primary Syphilis

– <u>Local</u>

- One or more ulcers (chancres) at inoculation site
- Painless
 - May go unnoticed
 - Often associated with regional or bilateral lymphadenopathy
- Occur 10 90 days after infection
- Highly infectious
- Resolves in 1-6 weeks





https://www.cdc.gov/std/syphilis/stdfact-syphilis.htm



Syphilis

- Classic Presentation
 - Single painless ulcer or chancre at the site of infection
- Atypical presentation
 - Multiple, atypical, or painful lesions at the site of infection

ORIGINAL ARTICLE

Painful and multiple anogenital lesions are common in men with *Treponema pallidum* PCR-positive primary syphilis without herpes simplex virus coinfection: a cross-sectional clinic-based study

Janet M Towns,¹ David E Leslie,² Ian Denham,¹ Francesca Azzato,² Christopher K Fairley,^{1,3} Marcus Chen^{1,3}







New York City Department of Health and Mental Hygiene, and the New York City STD Prevention Training Center. The Diagnosis and Management of Syphilis: An Update and Review. March 2019. A PDF version is available at www.nycptc.org.



Syphilis - Secondary

- Secondary Syphilis
 - Disseminated
 - <u>Systemic symptoms</u>
 - Dermatologic manifestations
 - Painless generalized adenopathy
 - Low-grade fever
 - Fatigue
 - Usually, 4-8 weeks after infection
 - Resolves in 6 weeks
 - Highly infectious







https://www.cdc.gov/std/syphilis/images.htm https://www.cdc.gov/std/syphilis/stdfact-syphilis.htm

Syphilis - Secondary

Organ System	Clinical Findings			
Skin and Mucous Membranes	 Rash or other skin lesions with varied appearance frequently on palms/soles Macular/papular/maculopapular Annular Psoriasiform Necrotic (rare) 			
	 Condyloma lata: moist, gray-white, wart-like growths appearing in warm moist areas such as the perineum and the anus Patchy alopecia, often with a moth-eaten appearance Mucous patches: flat, silver-gray discrete macules, plaques or erosions involving the mouth, tongue, or ano-genital mucosa Split- or fissured-papules at the angles of the mouth and nasolabial folds (rare) 			
Systemic	 Lymphadenopathy Systemic symptoms including: malaise, fever, and other nonspecific constitutional symptoms 			
Gastrointestinal	Gastric syphilis Hepatitis (usually subclinical)			
Renal	Glomerulonephritis Nephrotic syndrome			
Musculoskeletal	Arthritis Periostitis			
Neurologic	 Signs/symptoms of meningitis (eg, subtle headache) Cranial nerve (CN) dysfunction (especially 6th, 7th, 8th CN) Meningovascular syphilis with stuttering stroke symptoms 			
Ocular/Otic	 Symptoms of anterior, posterior, or panuveitis; other manifestations include episcleri vitritis, retinitis, papillitis, interstitial keratitis, acute retinal necrosis, and retinal detachm Symptoms of otologic syphilis (eg, hearing loss, tinnitus, vertigo) 			





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New York City Department of Health and Mental Hygiene, and the New York City STD Prevention Training Center. The Diagnosis and Management of Syphilis: An Update and Review. March 2019. A PDF version is available at www.nycptc.org.



Syphilis – Latent

Latent Phase	Definition			
Early Latent	Duration of infection <= 1 year			
Late Latent	Duration of infection >1 year			
Syphilis of Unknown Duration	Unknown duration of infection			
***Latent syphilis requires no exam findings of primary, secondary or tertiary syphilis				



Recommended Options for Treating Syphilis

Stage	Treatment	Alternative	
Incubation	Benzathine penicillin G 2.4 million	Doxycycline 100mg twice daily for 14 days	
Primary	units intramuscular injection once		
Secondary			
Early latent			
Late latent	Benzathine penicillin G 2.4 million	Doxycycline 100mg twice daily for 28 days	
Syphilis of unknown duration	units intramuscular injection 3 times		
Tertiary (non-neuro)	at one week intervals		
Neurosyphilis, Ocular, or Otic Syphilis	Aqueous crystalline penicillin G 18–24 million units per day, administered as 3–4 million units intravenously every 4 hours, or by continuous infusion, for 10–14 days	Procaine penicillin G 2.4 million units IM once daily <i>PLUS</i> Probenecid 500mg 4 times daily for 10–14 days	



Penicillin Shortage

enicillin G Benzathine Injectable Suspen Status: Currently in Shortage -Therapeutic Categories: Anti-Infective Expand all Pfizer Pharmaceuticals (Revised 07/10/2023) Therapeutic Categories: Anti-Infective Expand all **Company Contact Information:** 844-646-4398 Pfizer, Inc. (New 06/13/2023) Shortage Reas (per FDASIA) Availability and Estimated Shortage **Related Information Company Contact Information:** Duration 844-646-4398 Dear Patient Letter: Availability Update for Bicillin® L-A (penicillin G benzathine injectable suspension) and Bicillin L-A Pediatric 600,000 Units/mL Prefilled Next delivery: TBD; Estimated Demand Increas Bicillin® C-R (penicillin G benzathine and penicillin G procaine injectable suspension) Prefiled Syringes for the drug Presentation Posting Date Related Information Syringe (NDC 60793-700-10) recovery 2024 (HYPERLINK) 600,000 units/1 mL Prefilled Syringe (NDC 60793-130-10) 06/13/2023 Discontinuation of the manufacture of the drug On allocation. Check Wholesaler for Availability Bicillin L-A 1.2 million Units/2 mL (600,000 Dear Patient Letter: Availability Update for Bicillin® L-A (penicillin G benzathine injectable suspension) and Discontinuation of the manufacture of the drug Limited Supply. Next delivery: July 1.2 MU/2 mL Prefilled Syringe (NDC 60793-131-10) 06/13/2023 **Demand Increas** units/mL) Prefilled Syringe (NDC 60793-701-10) 2023; Estimated recovery: 02 2024 Bicillin® C-R (penicillin G benzathine and penicillin G procaine injectable suspension) Prefilled Syringes for the drug (HYPERLINK) On allocation. Check Wholesaler for Availability Dear Patient Letter: Availability Update for Bicillin@ L-A (penicillin G benzathine injectable suspension) and Bicillin L-A 2.4 million Units/4 mL (600,000 Limited Supply, Next delivery: July Demand Increase Bicillin® C-R (penicillin G benzathine and penicillin G procaine injectable suspension) Prefiled Syringes units/mL) Prefilled Syringe (NDC 60793-702-10) 2023; Estimated recovery: 02 2024 for the drug (HYPERLINK)



Recommended Options for Treating Syphilis

Stage	Treatment	Alternative	
Incubation	Benzathine penicillin G 2.4 million	Doxycycline 100mg twice daily for 14 days	
Primary	units intramuscular injection once		
Secondary			
Early latent			
Late latent	Benzathine penicillin G 2.4 million	Doxycycline 100mg twice daily for 28 days	
Syphilis of unknown duration	units intramuscular injection 3 times		
Tertiary (non-neuro)	at one week intervals		
Neurosyphilis, Ocular, or Otic Syphilis	Aqueous crystalline penicillin G 18–24 million units per day, administered as 3–4 million units intravenously every 4 hours, or by continuous infusion, for 10–14 days		



Managing Syphilis During Shortages



MONITOR SUPPLY AND FORECAST NEED

APPROPRIATELY STAGE SYPHILIS

PRIORITIZATION



Prioritization

Prioritization

- Pregnant persons
- Babies with congenital syphilis

Strategies

- Antimicrobial stewardship
- Alternative regimens
 - Doxycycline



Prioritization Strategies

		spital of Columbia a Therapeutics Comm	nd Cornell		
	DRUG				
ol. 43, No.6				June 2023	
Critical Dru	g Shortage: Penicil	llin G Benzathir	ne (Bicillin	[®] LA) Injection	
patients unable to rece Effective immediately	vive an alternative regimen a <u> y</u>, penicillin G benzathine (ge, the Department of Pharr	and must be approved (Bicillin® LA) will req	by an Infectious uire ID approv	lies should ONLY be used in s Diseases approval source. al prior to use. eatment of patients exposed	
		nancy	1	All Others	
Syphilis Exposure Primary Syphilis Secondary Syphilis	Benzathine penicillin G 2. Benzathine penicillin G 2.	4 million units IM x 1	Doxycycline 10 Benzathine peni	cline 100mg twice daily for 14 days hine penicillin G 2.4 million units IM x 1	
Early latent syphilis Late latent syphilis Tertiary syphilis (without neurol involvement)	Benzathine penicillin G 2. Benzathine penicillin G 2.			Omg twice daily for 28 days cillin G 2.4 million units IM x 3	
Neuro, Ocular, Otic syphilis	Aqueous crystalline penic per day, IV 10-14 days Please reach out to Pedia		Aqueous crystal per day, IV 10-1	line penicillin G 18- 24 million units 4 days	
	T lease reactif out to F edia	inte intectional Diabases	utilized at this	time. The following therapies	
Congenital syphilis For all other indication	matives to penicillin G benzi	athine:	uunzeu ar uns		
Congenital syphills For all other indication may be utilized as alte Potential Indication for	matives to penicillin G benzi	athine: tive Antibiotic Therapy		Comments	
Congenital syphilis For all other indication may be utilized as alte	matives to penicillin G benzi	athine: tive Antibiotic Therapy Children / au Children 12 years of Penicillin VK 25-50 m grams) PO divided qt Of Confuserer 60 A	dolescents Fage Ig/kg/day (max 3 S-8h R g/kg IM/IV q24h Fage mg PO q6-8h R	Comments In children, amoxicilin (50 mg/kg/day divided q12-24h) is another alternative	

For questions regarding this Drug Alert, please contact the NYP Enterprise Drug Information Center at 746-0741

or via email: druginformation@nyp.org

- 1. Recommendations:
 - 1. Requires ID approval
 - 2. Provide recommendations
 - 3. Provide alternatives
 - "For all other indications, alternatives to penicillin G benzathine MUST be utilized....



Provide Recommendations

	Pregnancy	All Others	
Syphilis Exposure	Benzathine penicillin G 2.4 million units IM x 1	Doxycycline 100mg twice daily for 14 days	
Primary Syphilis	Benzathine penicillin G 2.4 million units IM x 1	Benzathine penicillin G 2.4 million units IM x 1	
Secondary Syphilis		and a set of the set o	
Early latent syphilis			
Late latent syphilis	Benzathine penicillin G 2.4 million units IM x 3	Doxycycline 100mg twice daily for 28 days	
Tertiary syphilis (without neurological involvement)	enzathine penicillin G 2.4 million units IM x 3 Benzathine penicillin G 2.4 million units IM x		
Neuro, Ocular, Otic syphilis	Aqueous crystalline penicillin G 18- 24 million units per day, IV 10-14 days	Aqueous crystalline penicillin G 18- 24 million units per day, IV 10-14 days	
Congenital syphilis	Please reach out to Pediatric Infectious Diseases		



Provide Alternatives

Potential Indication for	Alternative Antibiotic Therapy		
Penicillin G benzathine	Adults	Children / adolescents	Comments
Treatment of Group A Streptococcal Pharyngitis	Penicillin VK 500 mg PO q8h x 10 days	Children <12 years of age Penicillin VK 25-50 mg/kg/day (max 3 grams) PO divided q6-8h OR Ceftriaxone 50-75 mg/kg IM/IV q24h Children ≥12 years of age Penicillin VK 125-250 mg PO q6-8h OR Ceftriaxone 50-75 mg/kg IM/IV q24h (all x 10 days)	In children, amoxicillin (50 mg/kg/day divided q12-24h) is another alternative
Prophylaxis of rheumatic fever	Penicillin VK 500 mg PO q8h x 10 days	<u>Children <5 years of age</u> Penicillin VK 125 mg PO q12h <u>Children ≥5 years of age</u> Penicillin VK 250 mg PO q12h	


Alternative Therapies for Group A Strep

Medication	Pediatric Dosing (max at adult dosing)	Adult Dosing	
Penicillin V	≤ 27 kg: 250 mg PO 2 to 3 times daily x10 days >27 kg: 500 mg PO 2 to 3 times daily x10 days	500 mg PO twice daily x10 days	
Amoxicillin	50 mg/kg/day PO once daily or divided twice daily x10 days	500 mg PO twice daily or 1 gram once daily x10 days	
Cephalexin	40 mg/kg/day PO divided twice daily x10 days	500 mg PO twice daily x10 days	
Ceftriaxone*	50 mg/kg IM x1 dose	Ceftriaxone 1g IV or IM x 1 or 2 doses	
Azithromycin**	12 mg/kg/day PO daily x5 days	500 mg PO daily x5 days	
Clindamycin**	7 mg/kg/dose PO three times daily x10 days	300 mg PO three times daily x10 days	
* Limited data available, only for patients unable to tolerate oral medications **Reserved for patients with anaphylaxis to penicillin/cephalosporins			



- Ceftriaxone
- Azithromycin
- Amoxicillin +/- Probenecid



- Ceftriaxone
- Azithromycin
- Amoxicillin +/- Probenecid

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- Ceftriaxone 1g IM/IV x 10 days
 - Limited data on effectiveness
 - "the optimal dose and duration of ceftriaxone therapy have not been defined"
 - "treatment decisions should be discussed in consultation with a specialist"



- Ceftriaxone
- Azithromycin
- Amoxicillin +/- Probenecid

- 2g Azithromycin x 1
- *"T. pallidum* chromosomal mutations associated with azithromycin and other macrolide resistance and documented treatment failures in multiple U.S. geographic areas, <u>azithromycin should</u> <u>not be used as treatment for syphilis</u>"



- Ceftriaxone
- Azithromycin
- Amoxicillin +/- Probenecid

 Observational Study
 > Clin Infect Dis. 2015 Jul 15;61(2):177-83. doi: 10.1093/cid/civ270.

 Epub 2015 Mar 31.
 Clin Infect Dis. 2015 Jul 15;61(2):177-83. doi: 10.1093/cid/civ270.

Clinical Infectious Diseases

MAJOR ARTICLE





Combination of Amoxicillin 3000 mg and Probenecid Versus 1500 mg Amoxicillin Monotherapy for Treating Syphilis in Patients With Human Immunodeficiency Virus (HIV): An Open-Label, Randomized, Controlled, Non-Inferiority Trial

Naokatsu Ando,^{1,0} Daisuke Mizushima,¹ Kazumi Omata,² Takashi Nemoto,³ Natsumi Inamura,³ Saori Hiramoto,³ Misao Takano,¹ Takahiro Aoki,¹ Koji Watanabe,^{1,0} Haruka Uemura,¹ Daisuke Shiojiri,¹ Yasuaki Yanagawa,^{1,0} Junko Tanuma,¹ Katsuji Teruya,¹ Yoshimi Kikuchi,¹ Hiroyuki Gatanaga,¹ and Shinichi Oka¹

¹AIDS Clinical Center, National Center for Global Health and Medicine, Tokyo, Japan; ²Center for Clinical Sciences, National Center for Global Health and Medicine, Tokyo, Japan; and ³Department of Laboratory, National Center for Global Health and Medicine, Tokyo, Japan;

Kazuhiko Ikeuchi 🥯 , Kazuaki Fukushima, Masaru Tanaka, Keishiro Yajima, Akifumi Imamura



Syphilis Treatment With Amoxicillin



Clinical Infectious Diseases

https://doi.org/10.1093/cid/ciad278

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Ando N, Mizushima D, Omata K, et al. Combination of Amoxicillin 3,000 mg and Probenecid versus 1,500 mg Amoxicillin Monotherapy for Treating Syphilis in Patients with HIV: an Open-Label, Randomized, Controlled, Non-Inferiority Trial [published online ahead of print, 2023 May 9]. Clin Infect Dis. 2023;ciad278. doi:10.1093/cid/ciad278



Treating Syphilis in Pregnancy

Stage	Treatment	Alternative	
Incubation	Benzathine penicillin G 2.4 million units intramuscular injection once		
Primary			
Secondary			
Early latent			
Late latent	Benzathine penicillin G 2.4 million units	"Pregnant [persons] who have a history of penicillin	
Late of unknown duration	intramuscular injection 3 times at one	allergy should be desensitized and treated	
Tertiary (non-neuro)	week intervals		
Neurosyphilis, Ocular, or Otic Syphilis	Aqueous crystalline penicillin G 18–24 million units per day, administered as 3– 4 million units intravenously every 4 hours, or by continuous infusion, for 10– 14 days	with penicillin"	

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Missed Doses

- How many days between doses is acceptable?
 - Clinical experience suggests that 10–14 days between doses of benzathine penicillin for latent syphilis might be acceptable before restarting
 - An interval of 7–9 days between doses is preferred
- How many days between doses is acceptable for pregnant persons?
 - "Missed doses >9 days between doses are not acceptable for pregnant [persons] receiving therapy for late latent syphilis"
 - "Pregnant [persons] who miss a dose of therapy should repeat the full course of therapy"



Follow-up After Treatment

Primary and Secondary

- Repeat serology
 - 6 months
 - 12 months

Signs of Failure

- Clinical signs and symptoms
- 4x increase in non-treponemal testing for >2 weeks
- Failure to see a 4x decrease after 12 months
 - 10%–20% will not achieve 4x
 decrease in titer within 12 months



Follow-up After Treatment

Latent

- Repeat serology
 - 6 months
 - 12 months
 - 24 months

Signs of Failure

- Clinical signs and symptoms
- 4x increase in non-treponemal testing for >2 weeks
- Failure to see a 4x decrease after 24 months
 - More common if initial titer is <1:8</p>



Follow-up After Treatment "Failure"

- Management of Treatment Failure
 - Follow-up
 - Serologic follow-up annually
 - Clinical (and particularly neurologic) examination
 - -Consider LP for CSF examination
 - Repeat HIV testing
 - If additional follow-up cannot be ensured, consider re-treatment



NYC STD Prevention Training Center

The CDC-funded NYC STD Prevention Training Center at Columbia University provides a continuum of education, resources, consultation and technical assistance to health care providers, and clinical sites. <u>www.nycptc.org</u>



Webinars, conferences, trainings and grand rounds presentations to enhance and build knowledge

Technical Assistance

Virtual and on-site technical assistance regarding quality improvement, clinic implementation and best practices around sexual health provision

> For more information please contact: Gowri Nagendra Soman MPH gn103@cumc.columbia.edu

Clinical Consultation Warmline

Clinical guidance regarding STD cases; no identifying patient data is submitted https://www.stdccn.org/

Resources

Clinical guidance tools regarding the STD treatment guidelines, screening algorithms and knowledge books, such as the **Syphilis Monograph**.

To download a copy please visit: http://bit.ly/SyphilisMonograph2019PTC



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March 2019

The Diagnosis,

Prevention of Syphilis

An Update and Review

Management and

Questions





Questions & Discussion



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Quick Evaluation

- 1. How would you rate the value of today's discussion?
- 2. The level of the brief lecture was:
- 3. Attending the learning community is a good use of my time.
- 4. I felt comfortable contributing during the LC session.
- 5. As a result of today's session, are there any changes you would make in your practice?
- 6. Since the last LC, has your clinic made (or is in the process of making) any clinical practice changes related to HIV prevention services?



Next Learning Community Session

Date: December 12, 2023

12-1pm EST

Topic: Doxy PEP



COLUMBIA VAGELOS COLLEGE OF PHYSICIANS AND SURGEON

In the meantime...

Look out for our October newsletter!

Feedback?

Questions for a clinician?

Let us know!

COLUMBIA

Find LC resources here:

https://nycptc.org/hivprevent.html

HIV PREVENTION LEARNING COMMUNITY



Bimonthly Newsletter

9 JUNE 202



June Newsletter

PRIDE MONTH

We love June because that means...it's Pride Month! We hope everyone has found resources to support campaigns your clinics and organizations are running this month. There are many great resources out there!

CDC has <u>"Pride-In-A-Box"</u>, a how-to guide with information and resources to support your site's Pride Month activities. You can also find their social media toolkit <u>here</u>.

You can find some other great resources and ideas from <u>GLSEN</u>, <u>The Trevor Project</u>, and <u>Human Rights Campaign</u>.

MAY LC RECAP

May's LC focused on **PrEP for Adolescents**. Together we discussed what PrEP options are available for adolescents, considerations when working with adolescents, and how newer PrEP options, like on-demand dosing and injectable PrEP, might or might not work for this population.

Some of the persistent concerns discussed included confidentiality when billing insurance, how to keep adolescents engaged in care, and addressing stigma among young people.

Are you interested in providing PrEP for adolescents? Let us know; we would love to help.



VAGELOS COLLEGE OF Physicians and Surgeons