

SB 306: Expanded Access to Expedited Partner Therapy (EPT) for Pharmacists

June 15, 2023

Eric Tang, MD MPH

Melissa Reyna, MPH

Clint Hopkins, PharmD, RPh, APh

Financial Disclosure

The speakers do not have any financial disclosures to share.

CPhA, Essential Access Health and the coordinators for this activity do not have any financial disclosures to share.



ACPE Information

The California Pharmacists Association (#0113) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

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Activity Type: Knowledge-based

Target Audience: Pharmacists

Release Date: 06/15/2023

Expiration Date: 06/15/2027

CE Objectives

At the completion of this activity, pharmacists will be able to:

- 1) Describe what Expedited Partner Therapy (EPT) is and why pharmacists should fulfill EPT prescriptions.
- 2) Describe the importance of EPT in reducing the community burden of Sexually Transmitted Infections.
- 3) Recall current CA legislation, with a focus on SB 306, supporting the use of EPT.
- 4) Identify strategies to offer EPT in pharmacy.

The Importance of Expedited Partner Therapy (EPT) for Sexually Transmitted Infections



Eric Tang, MD, MPH (he/him)

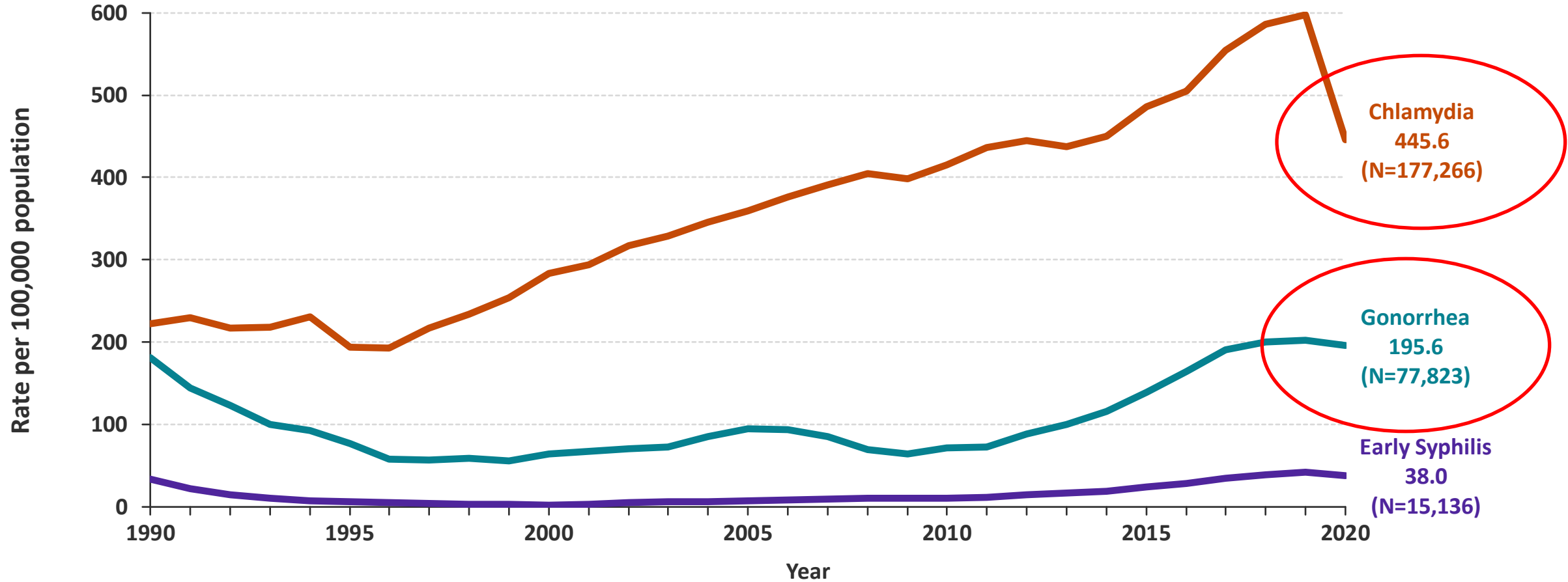
Chief, Medical & Scientific Affairs Section | Sexually Transmitted Diseases Control Branch
California Department of Public Health

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Disclosure Information

- I have no relevant financial relationships with an entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on patients

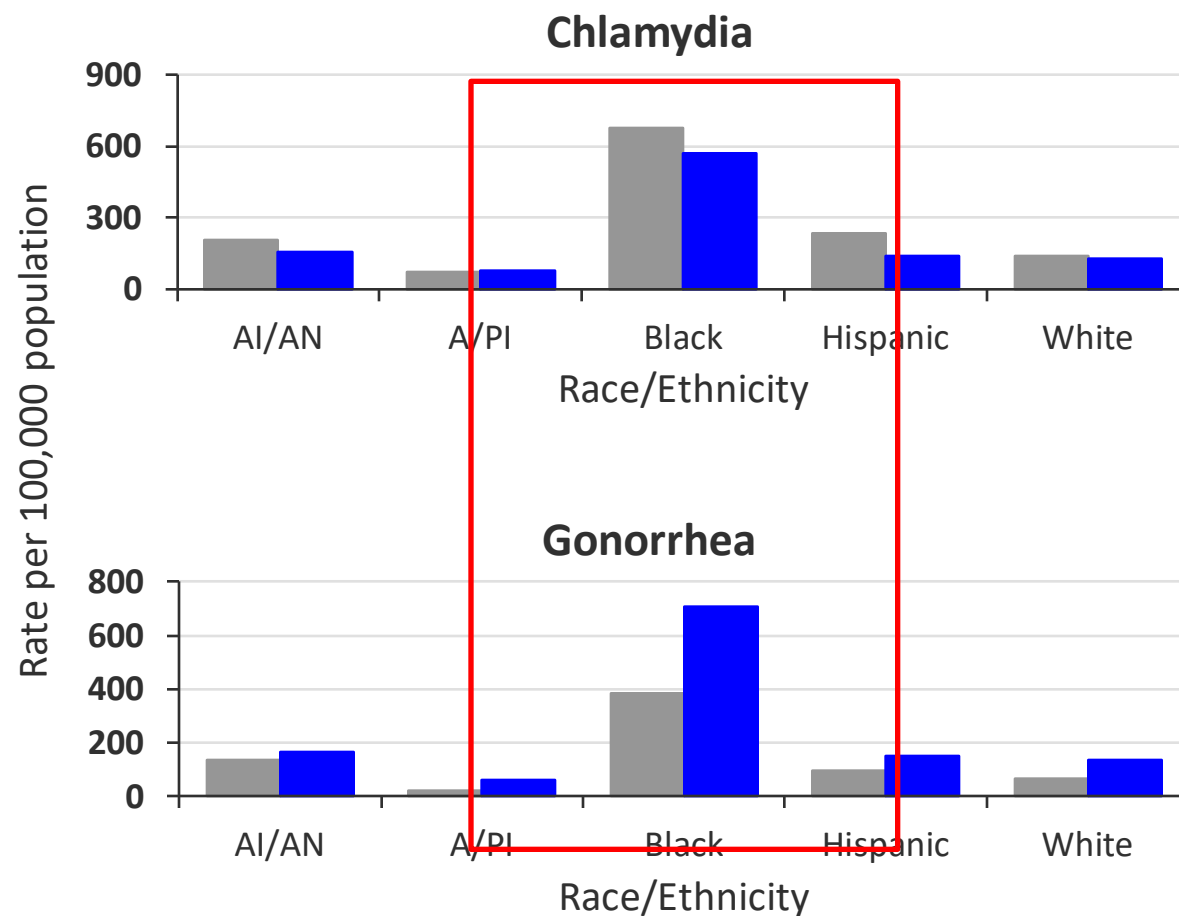
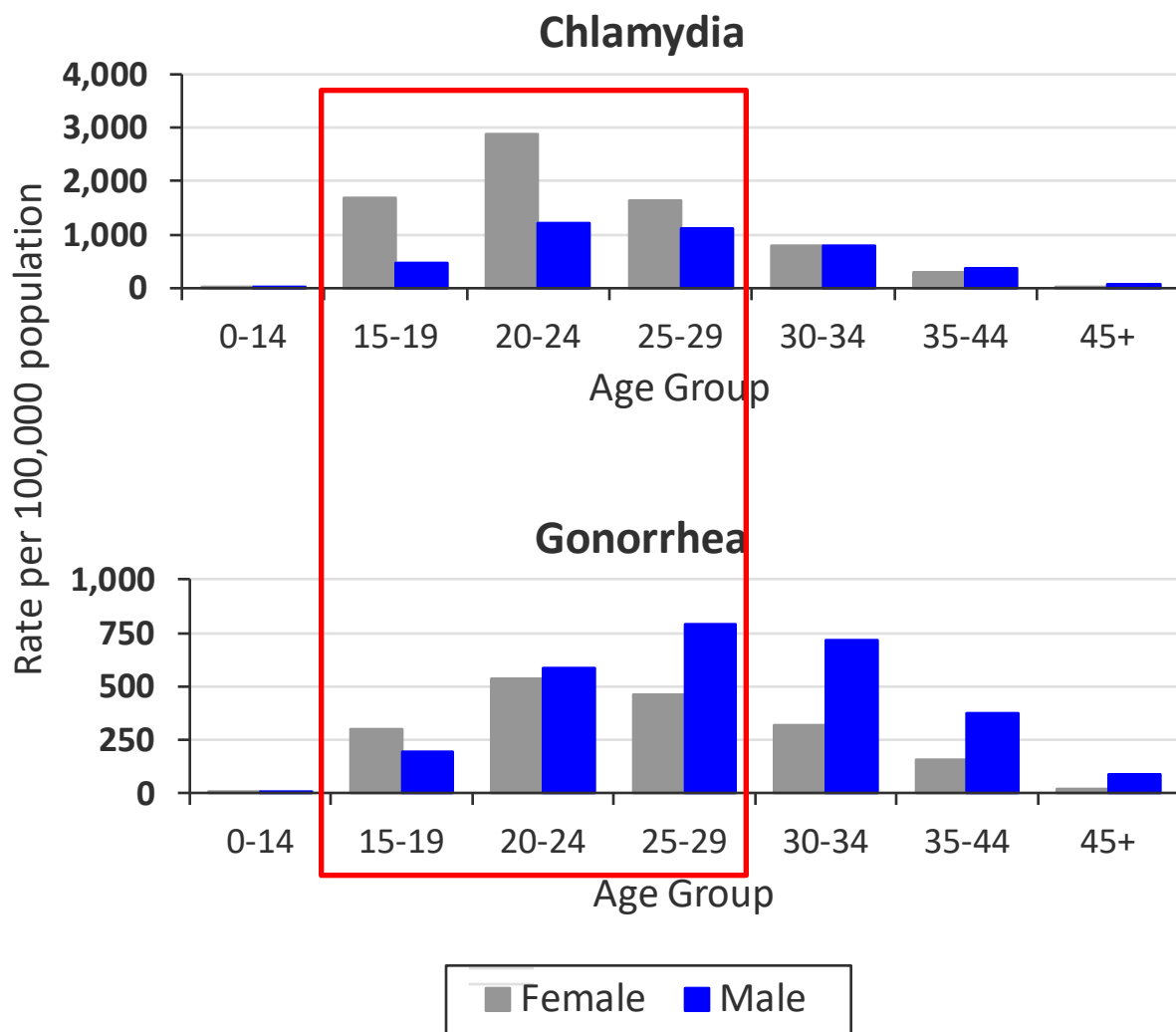
Chlamydia, Gonorrhea, and Early Syphilis* California Incidence Rates, 1990–2020



* Early syphilis includes primary, secondary, and early non-primary non-secondary syphilis.

(Revised 04/2022)

Rates of Chlamydia & Gonorrhea by Age, Race/Ethnicity & Gender, California 2020



Note: AI/AN = American Indian/Alaska Native, A/PI = Asian/Pacific Islander

Effective STI management requires treatment of their partners

- **Effective clinical management of STIs requires not only that the patient be treated, but also that their sex partners be treated to prevent reinfection and further transmission.**
- STI re-infection rates are high and have serious consequences
 - Up to 14% of people with chlamydia and 12% of people with gonorrhea become reinfected within 12 months of treatment, often through untreated partners¹
 - Recurrent chlamydia infections increases the risk of hospitalization for ectopic pregnancy and pelvic inflammatory disease²



¹Hosenfeld et al., 2009; Sex Transm Dis.

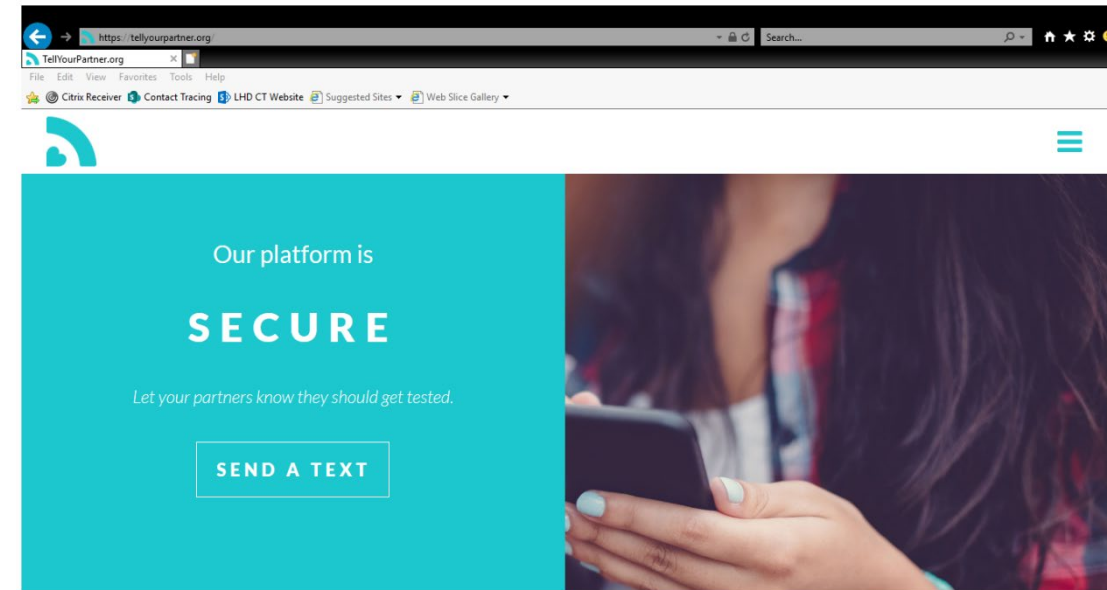
²Hillis et al, 1997; Am J Obstet Gynecol

Partner Management Recommendations for Chlamydia/Gonorrhea

- Presumptively treat **all** sexual partners from the **last 60 days**
- Work with the patient to get **all** partners presumptively treated:

- * **Patient brings partner to clinic**
- * **Expedited partner therapy (EPT)**

- Patient refers partner for testing
- Anonymous partner notification
- Provider referral
- Local health department referral



tellyourpartner.org

- * = **most effective at getting partners treated and reducing reinfections**

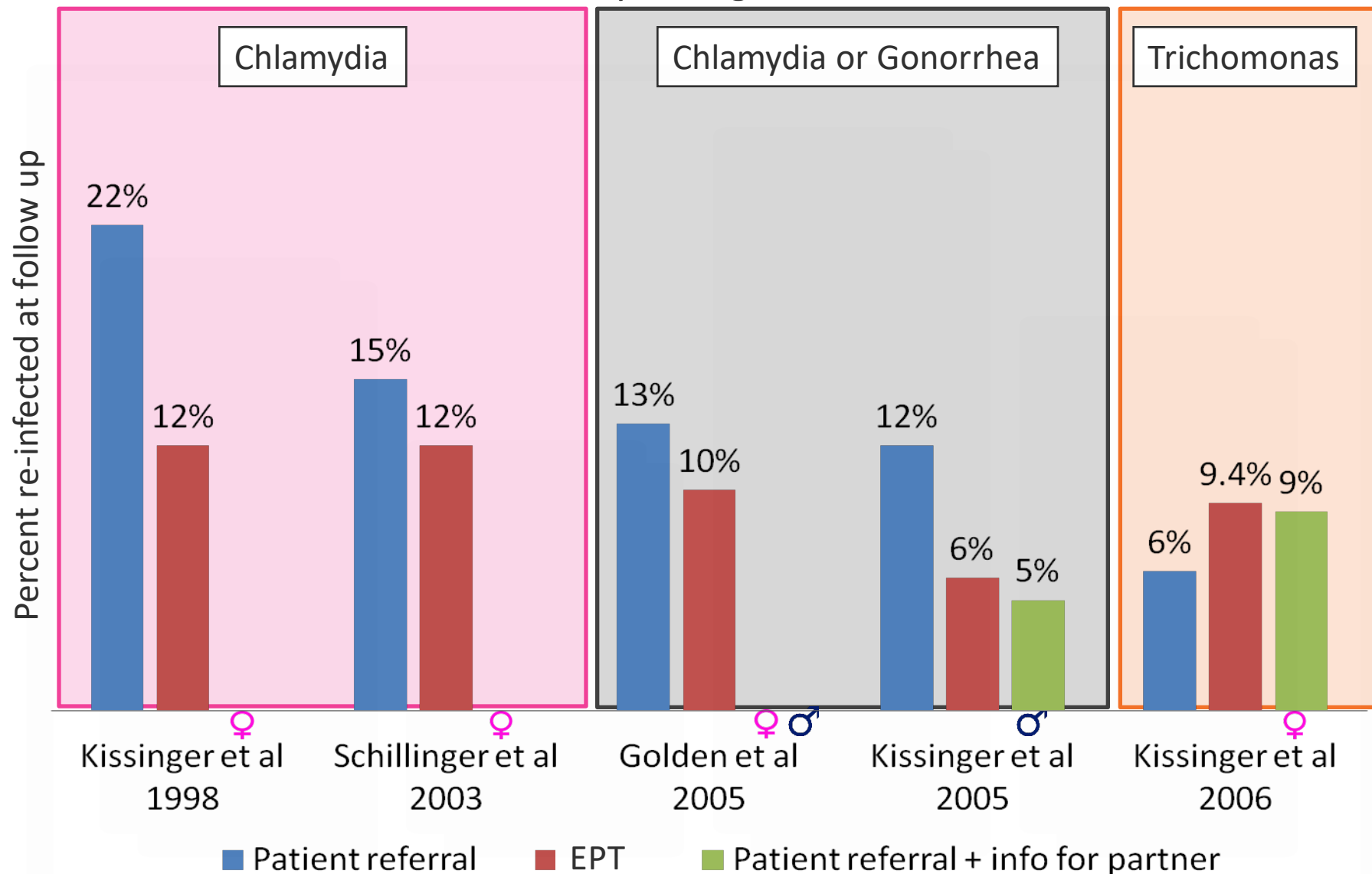
What is Expedited Partner Therapy (EPT)?

- The clinical practice of treating sex partners of patients diagnosed with certain STIs by providing medications or prescriptions to the partner(s) without examining the sexual partner(s)
- Occasionally referred to as partner-delivered partner therapy (PDPT)
- Usually involves the patient delivering the medication or a prescription to their partner(s)
- Harm-reduction and evidence-based approach for cases where partners are **unable or unlikely** to seek care in a clinical setting
- Used for chlamydia, gonorrhea, and trichomoniasis



EPT Effectiveness in Randomized Controlled Trials

Reduces reinfection with chlamydia & gonorrhea, but not trichomoniasis



Source: Trelle S, et al. Improved effectiveness of partner notification for patients with sexually transmitted infections: systematic review. *BMJ*. 2007;334:354.

CDC 2021 STI Treatment Guidelines

Chlamydia: “Routinely offer EPT to patients with chlamydia when the provider cannot ensure that all of a patient’s sex partners from the previous 60 days will seek timely treatment”

Gonorrhea: “EPT for gonorrhea should be offered to partners unlikely to access timely evaluation after linkage to care [for the partner(s)] is explored”

Trichomoniasis: “EPT also might have a role in partner management for trichomoniasis ...however, no partner management intervention has been demonstrated to be superior in reducing reinfection rates”

Syphilis: “No data support use of EPT in routine management of patients with syphilis”

Recommended EPT Regimens

For Chlamydia:

- Doxycycline 100 mg PO BID x 7 days is preferred unless the partner is pregnant
- Azithromycin 1 gm PO x 1 is less effective, especially for rectal chlamydia, but can be used in partners who are pregnant or unlikely to adhere to a 7-day course of therapy

For Gonorrhea:

- Cefixime 800 mg PO x 1

For trichomoniasis:

- Partner(s) at risk of cervicovaginal infection: Metronidazole 500 mg PO BID x 7 days
- Partner(s) at risk of penile infection: Metronidazole 2 gm orally x 1

- Can be provided to people regardless of gender and sexual orientation
- Ideally provided as packaged oral medications (vs a prescription) with treatment instructions and patient/partner education materials
 - Essential Access Health has resources you can use in English & Spanish: <https://www.essentialaccess.org/pdpt/resources>



It wasn't easy hearing about this, but I'm glad I got treated right away.

Chlamydia: What You Should Do Now

Your sex partner has chlamydia (kla-MID-ee-a).

This is a curable infection people can get from having sex. You may have chlamydia, too.

Your partner has taken medication to cure chlamydia. You should also be seen and tested by a doctor for sexually transmitted infections (STIs) and it is recommended you take a medication to treat chlamydia as soon as you can.

Here's what you need to know:

- Chlamydia is easy to cure. But both you and your partner(s) must take the medicine as indicated as soon as possible.
- You can get chlamydia by having sex with the penis, vagina, or anus. You can also get it by having oral sex (mouth on penis

Take Home Points

- While preferable for partners to come into a clinic for their own medical evaluation, when unlikely, EPT is an **allowable, recommended, safe, and evidence-based** alternative to ensure patient's partners receive treatment
 - Prevents reinfection and serious health consequences to the patient
 - Mitigates further transmission of STIs and the trend of increasing STIs in California



Expedited Partner Therapy (EPT) – Senate Bill (SB) 306 and Billing Policies



Melissa Reyna, M.P.H. | Lead STD Policy Analyst
Sexually Transmitted Diseases (STD) Control Branch
California Department of Public Health (CDPH)



Disclosure/Disclaimer

- I have no disclosures.
- The information reviewed in this presentation does not constitute legal advice and medical providers/pharmacists should review the law in its entirety for more information.

SB 306 Overview

SB 306 (Pan, Chapter 486, Statutes of 2021)

- Chaptered by the Secretary of State on October 4, 2021 and became law effective January 1, 2022
- Key Provisions

Defines EPT

Expands Conditions Allowable Under EPT

Allows Use of Standing Orders for EPT

Outlines EPT Prescription Labeling and Fulfillment Guidelines

Summarizes EPT Liability Protections

Key Provisions – Definition of EPT

Defines EPT

Expands Conditions Allowable Under EPT

Allows Use of Standing Orders for EPT

Outlines EPT Prescription Labeling and Fulfillment Guidelines

Summarizes EPT Liability Protections

- Providers who diagnose sexually transmitted infections (STI), as specified under existing law, can prescribe, dispense, furnish, or prescribe antibiotics to the patient's partner(s) without examining them.

Key Provisions – Expansion of EPT

Defines EPT

Expands Conditions Allowable Under EPT

Allows Use of Standing Orders for EPT

Outlines EPT Prescription Labeling and Fulfillment Guidelines

Summarizes EPT Liability Protections

- Expands the use of EPT so that it now includes any STI as recommended in the most recent Centers for Disease Control and Prevention (CDC) guidelines for the prevention or treatment of sexually transmitted diseases.

Key Provisions – Use Standing Orders for EPT

Defines EPT

Expands Conditions Allowable Under EPT

Allows Use of Standing Orders for EPT

Outlines EPT Prescription Labeling and Fulfillment Guidelines

Summarizes EPT Liability Protections

- Allows the following providers to use a standing order to prescribe, dispense, and furnish EPT medications
 - Physicians and Surgeons
 - Nurse Practitioners
 - Certified Nurse-Midwives
 - Physician Assistants

Key Provisions – EPT Prescription Labeling & Fulfillment Guidelines

Defines EPT

Expands Conditions Allowable Under EPT

Allows Use of Standing Orders for EPT

Outlines EPT Prescription Labeling and Fulfillment Guidelines

Summarizes EPT Liability Protections

- Requires a health care provider to include “expedited partner therapy” or “EPT” on a prescription if they do not have the name of a patient’s partner(s)
- A pharmacist may dispense and label the drug without the name of an individual for whom the drug is intended if the prescription includes the words “expedited partner therapy” or “EPT.”

Key Provisions – EPT Liability Protections

Defines EPT

Expands Conditions Allowable Under EPT

Allows Use of Standing Orders for EPT

Outlines EPT Prescription Labeling and Fulfillment Guidelines

Summarizes EPT Liability Protections

- Protects health care providers from medical malpractice action or professional disciplinary action, and pharmacists from civil, criminal, or administrative action, if the use of EPT is in compliance with the law, except in cases of intentional misconduct, gross negligence, or wanton or reckless activity.

Medi-Cal and Family Planning, Access, Care, and Treatment (PACT) Billing Policies



EPT in Medi-Cal and Family PACT

- Effective February 1, 2020 Medi-Cal and Family PACT updated their policy to reimburse for EPT
 - Often provided for chlamydia, gonorrhea, and trichomoniasis
 - Provides reimbursement for up to 5 partner doses per infection
 - The prescription needs to be written in the name of the beneficiary (Medi-Cal) or client (Family PACT).

Medi-Cal Preventative Services Manual

- “If a Medi-Cal provider diagnoses a Medi-Cal beneficiary with gonorrhea, chlamydia and/or trichomoniasis and determines that offering the beneficiary EPT is medically necessary to prevent reinfection of the beneficiary, then the provider may either dispense medication directly to the Medi-Cal beneficiary to provide to his/her partner(s) or may provide the Medi-Cal beneficiary with a prescription, **written in the name of the beneficiary**, for medications with a quantity and duration of therapy sufficient to treat the acute infection in the beneficiary and to prevent reinfection of the beneficiary by treating the beneficiary’s partner(s).”

Family PACT Benefits: Family Planning-Related Services Manual

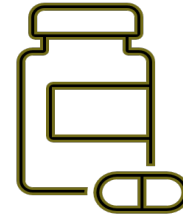
- “If a Family PACT provider diagnoses a Family PACT client with gonorrhea, chlamydia and/or trichomoniasis and determines that offering the client EPT is medically necessary to prevent reinfection of the client, then the provider may either dispense medication directly to the Family PACT client to provide to his/her partner(s) or may provide the Family PACT client with a prescription, **written in the name of the client**, for medications with a quantity and duration of therapy sufficient to treat the acute infection in the client and to prevent reinfection of the client by treating the client’s partner(s).”

Medi-Cal Encounters and EPT



Family Planning Encounters

- Treatment regimens for chlamydia, gonorrhea and/or trichomoniasis may be dispensed in the clinic



Non- Family Planning Encounters

- Treatment regimens for chlamydia, gonorrhea and/or trichomoniasis are covered by prescription only

Family PACT Clinical Practice Alert



Clinical Practice Alert March 2022

UPDATE: CHLAMYDIA AND GONORRHEA SCREENING AND TREATMENT

Screening is essential for detecting infection because a majority of women with chlamydia trachomatis (CT) and gonorrhea (GC) infections have no symptoms or signs. Early diagnosis and prompt management are intended to prevent reproductive complications including pelvic inflammatory disease (PID), tubal infertility, ectopic pregnancy, and chronic pelvic pain.



Routinely screen all sexually active females 24 years of age and younger annually for CT and GC.



Target CT and GC screening of females 25 years of age and older only to those with risk factors.



Retest CT- and GC-positive clients three months after treatment to detect re-infection. A test of cure should not be performed unless specifically noted.



Provide timely antibiotic therapy to all partners who had contact with the client during the 60 days prior to onset of symptoms or diagnosis of CT or GC. While a clinical evaluation of partners is preferred, patient delivered partner therapy and patients bringing in partners at the time of the treatment visit improves partner treatment rates.

QUESTIONS AND ANSWERS

Why does age influence routine screening compared to targeted screening for CT and GC?

Age is a strong predictor of risk for CT and GC infections, with the highest infection rates occurring in women aged 20 to 24 years, followed by females aged 15 to 19 years. Chlamydial infections are 10 times more prevalent than GC infections in young adult women.^{1,2}

- Discusses how partners should be managed
 - To facilitate partner notification and treatment, any client with laboratory-confirmed or presumptive chlamydia or gonorrhea infections should identify all sex partner(s) from the 60 days prior to the onset of symptoms or diagnosis. If the client's last sexual contact was over 60 days prior to diagnosis, the most recent sexual partner should be treated.

Medi-Cal and Family PACT – Billing for EPT Treatment*

Condition	Medication	Regimens	Dosage Form	Strength/ Package Size	Billing Unit	Utilization Management (UM) Type	ICD-10-CM Code	Clinic Code	Notes	Restrictions
Chlamydia	Azithromycin	1 gm PO X 1	Powder Packet	1 gm	each (ea)	QL	Z20.2 (STI[CT]-exposed partner) (M/F)	Q0144	Alternative regimen	Maximum of 6 grams per dispensing, and two (2) dispensings in rolling 30 days.
			Tablets/ Capsules	500 mg	ea					
	Doxycycline Hyclate	100 mg PO BID X 7days	Capsules/ Tablets	100 mg	ea		Z20.2 (STI[CT]-exposed partner) (M/F)	S5000/ S5001	Recommended regimen	Maximum of 84 tablets per dispensing, and two (2) dispensings in rolling 30 days.
	Doxycycline Monohydrate	100 mg PO BID X 7days	Capsules	100 mg	ea	QL	Z20.2 (STI[CT]-exposed partner) (M/F)	S5000/ S5001	Alternative regimen	Maximum of 84 tablets per dispensing, and two (2) dispensings in rolling 30 days
	Levofloxacin	500 mg PO QD X 7 days	Tablets	250 mg 500 mg	ea ea		Z20.2 (STI[CT]-exposed partner) (M/F)	S5000/ S5001	Alternative regimen	Maximum of 84 tablets (250 mg) or 42 tablets (500 mg) per dispensing, and two (2) dispensings in rolling 30 days
Gonorrhea	Cefixime	800 mg PO X 1	Tablets/ Capsules	400 mg	ea	QL	Z20.2 (STI[GC]-exposed partner) (M/F)	S5000/ S5001	Alternative regimen	Maximum 12 tablets/capsules (400 mg) per dispensing, and two (2) dispensings in rolling 30 days.
Trichomoniasis	Metronidazole	2 gm PO X 1	Oral Tablets	250 mg 500 mg	ea ea	QL	Z20.2 (STI [Trichomoniasis] – exposed partner) (M/F)	S5000/ S5001	Recommended regimen (Males)	Maximum of 84 tablets (500 mg) per dispensing, and one (1) dispensing in 15 days
	Metronidazole	500 mg PO BID X 7 days	Oral Tablets	250 mg 500 mg	ea ea	QL	Z20.2 (STI [Trichomoniasis] – exposed partner) (M/F)	S5000/ S5001	Recommended regimen (Females)	Maximum of 84 tablets (500 mg) per dispensing, and one (1) dispensing in 15 days

Note: This table summarizes information from various Medi-Cal and Family PACT Manuals and is subject to change due to manual updates.



Resources

- [Senate Bill 306 Fact Sheet - Expedited Partner Therapy \(EPT\) \(PDF\)](#)
- [Medi-Cal Family Planning Benefit Manual](#)
- [Medi-Cal Preventative Services Manual](#)
- [Medi-Cal Rx Contract Drugs List](#)
- [Family PACT Family Planning-Related Services Benefits Manual](#)
- [Family PACT Pharmacy Formulary](#)
- [Family PACT Onsite Dispensing Price Guide](#)



Thank you!

Questions? Comments?

Expedited Partner Therapy (EPT) Pharmacist Perspective

Clint Hopkins, PharmD, RPh, APh (he/him)

CEO / Pharmacist

Pucci's Pharmacy / Pucci's LTC Pharmacy

What will EPT Rxs look like?

- Some Rxs may have the name of the index patient only along with a total number of doses to treat all patients who could be potentially affected.
- Rx may have no name associated and still be filled so long as the Rx states "EPT" or Expedited Partner Therapy on the Rx
- Often phoned in by prescriber but may be eRx or paper Rx

Family PACT and Medi-Cal Rxs -

- May be written for the total number of doses to be dispensed under the index patient's name

AMY PRESCRIBER, M.D.		
Ph: 888-555-1234	234 Treatment Way	NPI: 1234567899
Fax: 888-555-5678	Sacramento, CA 95816	DEA: AP1234567
Name: <u>John Q. Patient</u>	DOB: <u>1/8/1990</u>	
Address: <u>123 Any St, Sacramento, CA</u>	Date: <u>9/1/2022</u>	
Rx: Doxycycline 100 mg Orally 2x/day for 7 days Please dispense in 3 labeled bottles of #14 for index patient and two partners		
Refill <u>0</u> Times <u>Amy Prescriber</u> M.D.		

Other Rx's (commercial plans, cash pay, etc.) -

- May be written for the medications to treat an individual patient but may not contain the person's name or their date of birth.

AMY PRESCRIBER, M.D.		
Ph: 888-555-1234	234 Treatment Way	NPI: 1234567899
Fax: 888-555-5678	Sacramento, CA 95816	DEA: AP1234567
Name: <u>Expedited Partner Therapy</u>	DOB: _____	
Address: <u>123 Any St, Sacramento, CA</u>	Date: <u>9/1/2022</u>	
Rx: Doxycycline 100 mg orally 2x/day for 7 days Disp #14		
Refill <u>0</u> Times <u>Amy Prescriber</u> M.D.		

What about insurance audits?



EPT Rx are valid as written under the authority of California Health and Safety Code § 120582



Additionally, medications prescribed for EPT are not high dollar claims and are not typically the target of PBM audits.



If you are audited on an EPT Rx, please let us know by contacting Essential Access Health at stdprograms@essentialaccess.org

California Business & Professions Code § 4076

“Notwithstanding subdivision (a) or any other law, a pharmacist may dispense a drug prescribed pursuant to Section 120582 of the Health and Safety Code and label the drug without the name of an individual for whom the drug is intended if the prescription includes the words ‘expedited partner therapy’ or the letters ‘EPT.’”

Provider-Pharmacist Relationships

- Providers find the Pharmacists in your area who are keen on sexual health
- Pharmacists find the Providers in your area who are keen on sexual health
- Network
- Collaborate
- Refer
- Make a Difference

Sources

"STI Treatment Guidelines." *Centers for Disease Control and Prevention*, 13 Sept. 2022, <https://www.cdc.gov/std/treatment-guidelines/default.htm>

Centers for Disease Control and Prevention. *Expedited partner therapy in the management of sexually transmitted diseases*. Atlanta, GA: US Department of Health and Human Services, 2006.

"Guidance on the Use of Expedited Partner Therapy in the Treatment of Gonorrhea." *Centers for Disease Control and Prevention*, 18 Aug 2021, <https://www.cdc.gov/std/ept/gc-guidance.htm>

"Legal Status of EPT in California." *Centers for Disease Control and Prevention*, 6 Jan. 2022, <https://www.cdc.gov/std/ept/legal/california.htm>

Questions?

Kala Heekin, STI Prevention Program Manager

kheekin@essentialaccess.org

Clint Hopkins, Pucci's Pharmacy

clint@puccirx.com