

Preventing Chlamydia and Gonorrhea Reinfection through Increased Use of Expedited Partner Therapy

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EXECUTIVE SUMMARY

The Centers for Disease Control and Prevention (CDC) reported more than 1.5 million chlamydia and 400,000 gonorrhea cases in 2015, mostly in adolescents and young adults.^{1,2} A relatively simple treatment can cure most patients of chlamydia and gonorrhea, but treating an infected patient is not always enough to keep them healthy. Patients treated for sexually transmitted infections (STI) are often at risk of being reinfected because their partners remain untreated. Persistent and recurring infections can cause serious and long-term health problems, including chronic pain and infertility.

Reinfection is common in patients diagnosed with chlamydia and gonorrhea. Other STIs, such as HIV and syphilis, trigger the use of comprehensive partner services through which providers and health departments find, notify and treat potentially infected partners. Limited resources usually do not permit this level of service for patients with chlamydia or gonorrhea.

Successful treatment of any STI patient must include treating infected partners. **When the partner is unwilling or unable to present for a clinical evaluation, expedited partner therapy (EPT) can be an important and effective treatment option.** EPT is the practice by which a clinician provides the patient with extra medication or a prescription to give directly to his or her partner. While clinical evaluation of the partner remains the ideal standard of care, EPT is widely supported by professional medical and legal organizations as a safe and effective way of preventing STI reinfection and further disease transmission.



EXPEDITED PARTNER THERAPY (EPT)

A patient-delivered partner therapy used to help prevent reinfection of chlamydia or gonorrhea by providing the patient with extra medication or a prescription to give to their sex partner(s) who are unwilling or unable to seek treatment.

Although most providers agree that EPT can help prevent reinfection and provide higher quality care for their patients, few actually report offering this service.³ A number of legal, financial and administrative barriers limit the use of this treatment option, and these barriers can vary significantly by state. This *Evidence to Action* brief identifies these barriers and offers recommendations for how states can improve the legal status surrounding EPT in order to provide safe practice environments for providers.

BACKGROUND

PREVALENCE OF CHLAMYDIA AND GONORRHEA

Chlamydia and gonorrhea are two of the most common STIs in the U.S. Rates of chlamydia and gonorrhea reached an all-time high in 2015 – increasing by 6% and 13% over 2014, respectively.¹ Many cases, however, go undetected and the CDC estimates that as many as 820,000 new gonorrhea infections actually occur each year. Rates are highest among adolescents and young adults ages 15–24.^{1,2} In high-risk urban adolescent populations, approximately 25% of girls acquire chlamydia within one year of becoming sexually active.⁴

Many people with chlamydia or gonorrhea will not experience any symptoms and may not know that they are infected, which makes it common to unknowingly spread infection. When symptoms do occur, they can be mild and include painful urination and abnormal discharge from the vagina or penis. Both gonorrhea and chlamydia, however, can cause serious health problems over time, particularly for women. If left untreated, both can lead to pelvic inflammatory disease (PID), which can cause permanent damage to a woman's reproductive system and result in chronic pelvic pain, infertility or ectopic pregnancy—a potentially life-threatening condition in which pregnancy occurs outside the uterus. There are approximately 750,000 cases of PID each year, with an estimated cost of \$1.5 billion.⁵ In rare cases, untreated infections can also lead to infertility in men.²

RISK OF REINFECTION

Although antibiotics can cure chlamydia and gonorrhea, reinfection is common and can increase the risk of developing long-term health problems. On average, 14% of women with chlamydia and 12% of women with gonorrhea will be reinfected, with younger women at higher risk.⁶ Many adolescents treated for either infection are reinfected within three to six months, usually because of resumed sexual contact with an untreated partner.⁷

CHALLENGES TO PARTNER TREATMENT

Resources are limited for comprehensive partner services, which include finding, notifying and treating the partner of a patient diagnosed with a STI. Provider referral—when a health care provider or health department contacts the partner for notification and referral for treatment—is considered the most effective first-line prevention strategy, but scarce resources generally limit this practice to cases involving HIV and syphilis. One survey of health departments found that providers interviewed less than one in five individuals treated for gonorrhea and chlamydia to identify their partners and complete partner notification and referral for treatment. The standard alternative to provider referral is the less effective patient referral, which relies on the patient to notify all of his or her partners at risk of infection and refer them for treatment.⁸

PREVENTING REINFECTION WITH EXPEDITED PARTNER THERAPY

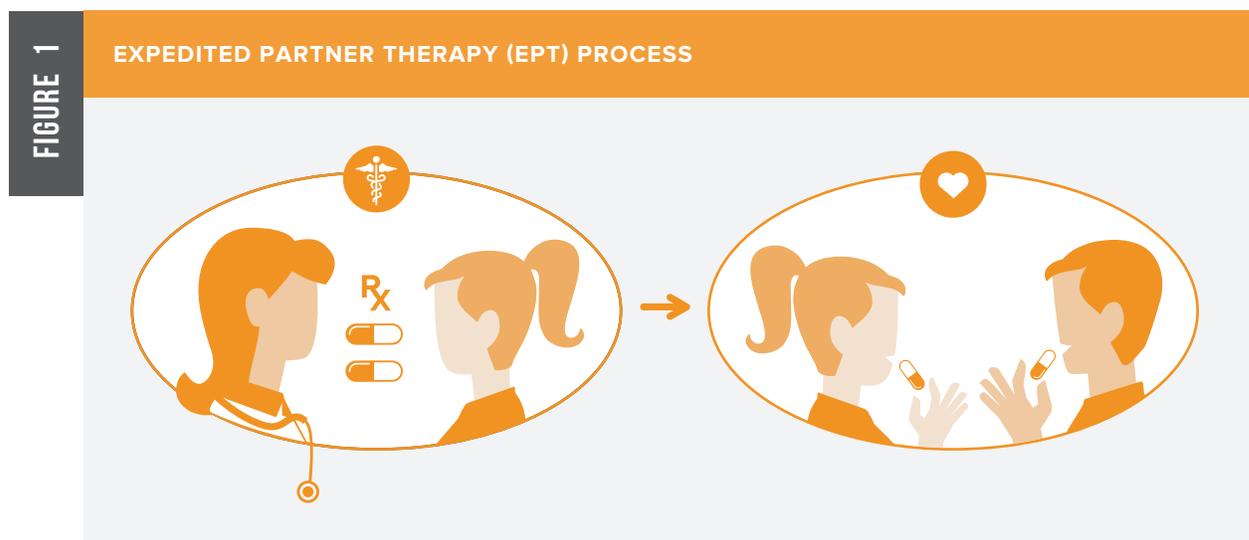
WHAT IS EXPEDITED PARTNER THERAPY?

EPT is a patient-delivered partner therapy used to help prevent reinfection of chlamydia or gonorrhea by providing the patient with extra medication or a prescription to give to their sex partner(s) who are unwilling or unable to seek treatment. EPT treats partners of patients with chlamydia or gonorrhea without an office visit, using a single course of oral antibiotics that rarely cause adverse side effects.

The recommended treatment for gonorrhea changed in 2012 due to the infection's growing resistance to some antibiotics—a combination of pills and an injection are now considered best practice. The CDC continues to

recommend EPT for treatment of gonorrhea, which includes oral antibiotics along with a referral for additional treatment via injection. While in-person evaluation and treatment is ideal for all partners at risk of infection, EPT can help to improve reinfection outcomes when an in-person visit is not plausible.⁹

EPT is recommended for use in heterosexual males and females with partners who are otherwise unlikely or unable to receive treatment.⁸ Insufficient data is available to recommend EPT for men who have sex with men or women who have sex with women.^{7,10}



EVIDENCE FOR EPT

The practice of EPT is widely supported by professional medical and legal organizations including the American Medical Association, American Academy of Family Physicians and American Bar Association.¹¹ The CDC's recommendation for EPT is the result of multiple U.S. clinical trials that showed an overall reduction in the rates of chlamydia reinfection by 20% and gonorrhea reinfection by 50% at follow-up appointments when compared with standard partner referral.¹²

Additionally, patients are at least as likely to choose and comply with EPT as they are with the standard patient referral method.¹³ A 2013 study showed that 85% of 13- to 22-year-old patients reported being likely or very likely to treat partners through EPT that provides either a written prescription or medication in hand. In this study, patients with greater acceptance of EPT had higher education levels and greater self-efficacy and treated a romantic partner rather than a friend or casual acquaintance.⁴

A 2014 retrospective study using data from patients who visited New York City clinics showed that EPT had high rates of actual acceptance. For patients whose partners were not already treated, the EPT acceptance rate was nearly 70%.¹⁴

Studies also suggest higher compliance is more likely with EPT than with standard partner referral, indicating that patients might be more likely to follow through with the recommended referral for treatment when they have the medication or prescription to give their partner.¹⁵ Because EPT (1) is at least as acceptable to patients as standard partner referral, (2) could have greater rates of compliance and (3) yields stronger results at follow-up

visits, regular use of EPT could successfully treat more partners of infected patients, help to prevent the spread of disease and reduce the rates of recurrent infection.

While most physicians agree that EPT is an effective way to help prevent spread of the disease and reinfection in their patients, many do not offer the treatment method themselves.³ EPT is often underutilized due to clinician misperceptions about its legality, financial and administrative challenges and concerns about treating minors. The following section addresses these barriers and highlights some possible solutions to increase access to EPT and improve patient outcomes.

THE CDC'S CASE FOR EPT

1. In a study with **men who tested positive for chlamydia or gonorrhea**, patients in the EPT group who were given the medication to provide to their sexual partners were 38% less likely to have a recurrent infection at one-month follow up than the group who used standard partner referral.¹⁶
2. A study of **men and women who tested positive for gonorrhea or chlamydia** evaluated the difference in outcomes between patients who received standard partner referral and those who received medication to provide to their sex partner(s). Results showed that EPT was more effective in three significant ways:¹⁷
 - a. Lower rates of recurrent or persistent infection at follow up (73% reduction for gonorrhea and 15% reduction for chlamydia),
 - b. Higher likelihood that the patient's partner or partners had been treated or tested negative and
 - c. More reports that the patient did not have sex with any potentially infected partners until after they received evaluation or treatment.
3. A study of **women who tested positive for chlamydia** showed that the risk of reinfection was 20% lower for those who received EPT compared with those who received standard partner referral information. These results suggest that EPT could be more effective than partner referral at decreasing the likelihood of reinfection.¹⁵

SOURCE: Centers for Disease Control and Prevention. 2015 Sexually Transmitted Diseases Treatment Guidelines: Clinical Prevention Guidance. Retrieved from <http://www.cdc.gov/std/tg2015/clinical.htm>.

BARRIERS AND SOLUTIONS TO EPT IMPLEMENTATION

1

BARRIER: INCONSISTENT AND UNCLEAR LAWS ACROSS STATES LEAD TO LIABILITY CONCERNS AND MISPERCEPTIONS FOR PROVIDERS.

In general, there are three legal environments in which to consider the practice of EPT: permissible, potentially allowable and prohibited.

- EPT is *permissible* if it is explicitly allowed by law, or if there are no rules that contradict its use. As of July 2016, EPT is permissible in 40 states and Washington, D.C. The exact legal status and the extent to which health care providers can practice EPT still varies among these states. Some states, such as Rhode Island and Wisconsin, have laws on record that explicitly allow physicians to prescribe medication to their patients' partners for chlamydia or gonorrhea without first evaluating the partner. Other states, such as Mississippi, have no laws or regulations clearly stating that EPT is legal, but also have no rules stating that it is not. Still other states, such as Massachusetts and Tennessee, allow EPT to treat chlamydia, but not gonorrhea.
- EPT is considered *potentially allowable* in eight states because the laws in place might be contradictory to one another or are simply unclear.
- EPT is *prohibited* in two states, Kentucky and West Virginia, as expressly written into law.^{18,19}

These numbers show significant improvement to the permissibility of this practice since 2008, when EPT was permissible in only 12 states, potentially allowable in 28 and prohibited in 13.²⁰

While more states than ever are allowing the use of EPT, the rapidly changing and often confusing legal status of EPT may contribute to health care providers' uncertainty about using this treatment method. A 2015 PolicyLab study explored the variation in provider practice of and attitudes toward EPT for 13- to 17-year-olds across nine states in three different policy environments

where EPT was: explicitly legal, permissible with no laws explicitly allowing it and potentially allowable with unclear laws or policies. It did not include states where EPT is prohibited. The study found that **most providers have poor knowledge of EPT policies and legality.** In the three states where the practice was explicitly legal, only half of the providers knew it. Additionally, the majority of providers in states where EPT is permissible or potentially allowable, 88% and 74% respectively, reported not knowing the legality of the practice at all.³ A separate study found similar knowledge gaps among pediatric residents in California, where EPT is explicitly legal for treatment of both chlamydia and gonorrhea. Only 8% of participants knew the legal status of EPT. More than two-thirds knew EPT could be used for chlamydia and gonorrhea, but up to 38% incorrectly thought it could be used for conditions for which the practice is not approved, such as trichomoniasis. The most reported barrier to providing EPT, cited by 87% of providers, was lack of familiarity with the law.²¹

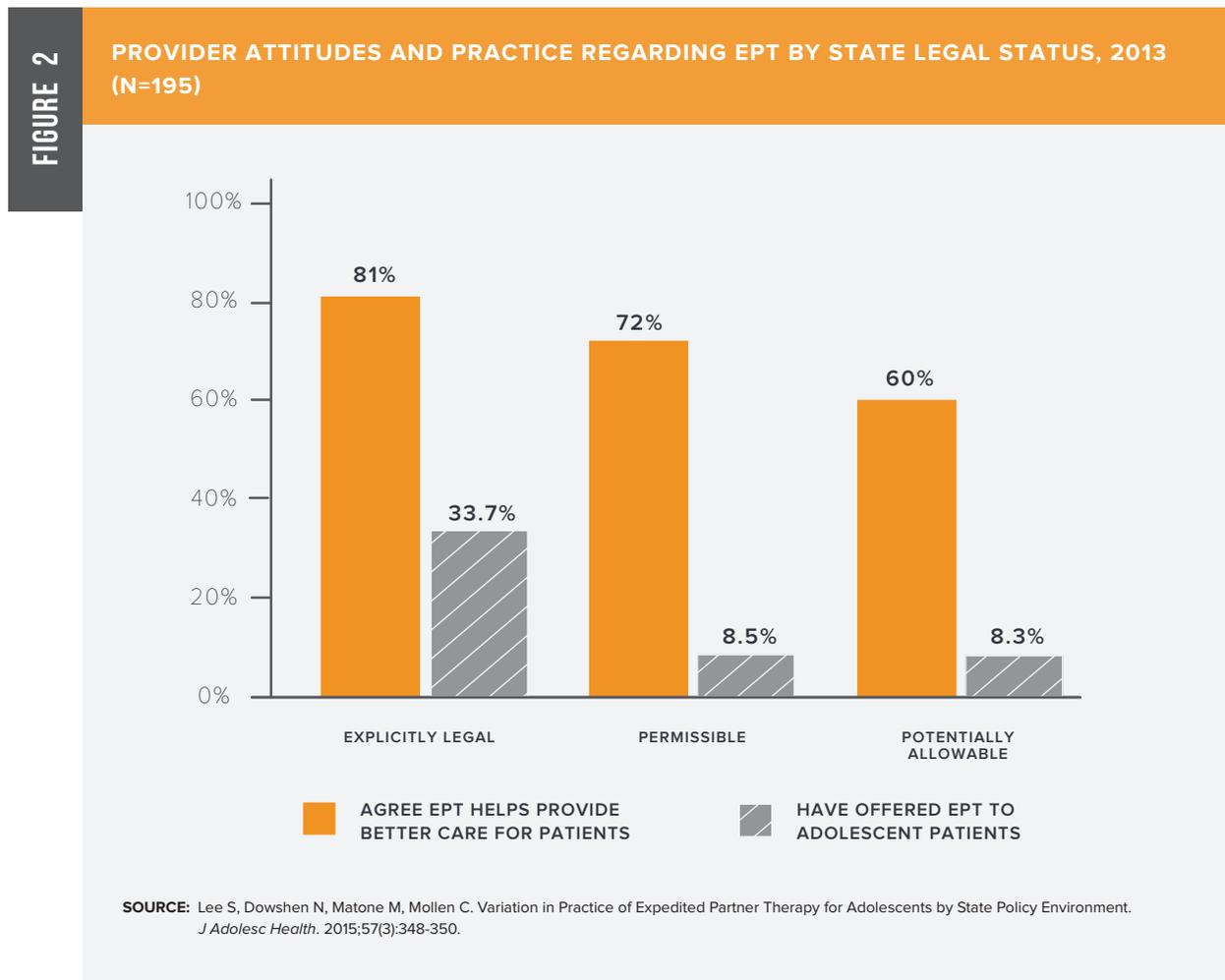
"I trained in a state where EPT was illegal, but when I moved to PA I learned that it was legal here so I started providing it. However, I was recently told that it is 'not exactly' legal, and so have stopped providing it. Clear information of the legality of this would really help!"

PA Health Care Provider¹⁸

As shown in Figure 2, while most providers in the PolicyLab study across all states agreed that EPT prevents the spread of infection and could help them provide better care to their patients, only 20% of all providers reported ever offering EPT to their adolescent patients. Providers in states where EPT is explicitly legal, however, were more likely to support the practice and to report having offered it to patients in the past. In states where EPT was explicitly legal, 33.7% of providers reported offering EPT to their

adolescent patients. Where EPT was permissible but with no explicit laws or potentially allowable with no clear laws or policies, the rates of EPT use were much lower at 8.5% and 8.3%, respectively.³

Uncertainty of the legal status of EPT can create a tension for health care practitioners between providing optimal care to achieve better outcomes for patients and risk of legal and professional liability.²²



SOLUTIONS

To ensure that health care providers are able to offer EPT as a treatment option, we must eliminate uncertainty regarding the legality of EPT and questions about their medical institution's support of the practice. The following actions could help to align laws and policies with widely recommended EPT practice and increase providers' likelihood of offering it to their patients:

The American Bar Association (ABA) should craft and share model legislation in support of EPT based on its 2008 policy statement.¹¹ The ABA has an active audience in every state. Providing each state with the same pre-crafted legislation that addresses the potential legal barriers to EPT could encourage changes to or clarification about its legal status, as well as more uniformity of the practice across the country.

Health care providers, medical associations and health departments should be public and vocal about their support for EPT. State-level advocates have reported that strong support from these groups can be influential in gaining legislative support to change or clarify policies so that it is less risky for providers to offer EPT.²³

State medical boards should adopt guidelines that are in line with nationally recommended EPT practice in order to support the passage of such statutes in the state. Almost every state can improve its standing law. Where EPT is permissible, potentially allowable or prohibited, lawmakers should make it explicitly legal. Where it is explicitly legal for chlamydia only, lawmakers should expand language to include gonorrhea, which will cover the full scope of the recommendation.

State health departments and medical boards should clarify their support of EPT and reassure providers that EPT meets the standard of care owed to their patients. Local health departments can also advocate to support EPT in their jurisdictions when state laws are unclear.

Health providers and systems should establish clear treatment pathways that support the use of EPT, unless explicitly prohibited by state law. This strategy is particularly important in states where the law is unclear or confusing. In addition to understanding the official legal status of EPT, it is important that providers also know whether their employer and colleagues support the practice in order to address the fear of professional censure.¹⁸

2

BARRIER: ADMINISTRATIVE CHALLENGES CAUSED BY RESTRICTIVE LAWS AND POLICIES CAN PREVENT THE PRACTICE OF EPT.

Health care providers who wish to utilize EPT, even in states where it is permissible, may be deterred by logistical challenges that make the practice cost prohibitive or overly complicated. For instance, **most states and medical institutions require that providers keep medical records for all patients who are given prescriptions.**⁷ EPT requires dispensing medicine or prescriptions to individuals who do not present for a clinical evaluation, so establishing a medical record may not be feasible. Therefore, even if EPT is legal in the state, this type of policy could make it challenging to find a legal way to dispense medication or prescriptions to patients' partners.

Many states require that prescription labels include the name and other identifying information of the recipient,¹⁹ but this information about the partner is not always made available to the prescribing provider.

Payment and reimbursement issues can be a disincentive for providers to offer EPT. Institutions that are able to dispense extra medication to treat the sex partners of their patients may face a financial loss because of insufficient reimbursement systems that do not allow payment for those services. Additionally, the practice of EPT can require added time to counsel the patient—or their sex partners if the provider chooses to reach out by phone as part of the EPT treatment plan—and this additional time is often not paid for.⁷

SOLUTIONS

Simplifying, standardizing and adequately covering the cost of carrying out EPT in states where the practice is allowed is key to ensuring it is a viable treatment option. Strategies to address these administrative challenges include the following:

Medical institutions should develop a process for creating medical records that document prescriptions for partners who are not physically seen in the practice for evaluation. While it is sometimes possible to document a prescription for the partner under the patient's medical record as a direct part of their treatment, providers may need to develop a process for recording prescriptions to partners where this is not allowed. For instance, a clinical advisory from the Massachusetts Department of Public Health offering guidelines for providers using EPT indicates that when an electronic medical record system does not permit prescription of EPT, an online information sheet is available to assist prescribers in writing the prescription.²⁴ Society for Adolescent Medicine and American Academy of Pediatrics chapters as well as state and local health departments can serve as potential resources to help providers develop this type of system.⁷

Health systems should establish billing codes to cover expenses related to extra medication and counseling time for EPT. The introduction of billing codes specifically for services related to EPT can simplify the treatment process and also serve as assurance to providers that the practice is a legal and supported standard of care. Physicians, medical institutions and public and private payers can take action by submitting applications to the CPT Editorial Panel at the American Medical Association to develop new or modify existing codes to include EPT services.²⁸

States should amend existing legislation to allow providers to write prescriptions without full identifying information of the partner when this information is not revealed to the provider. When prescriptions are necessary because providers are unable to directly dispense the medication, this type of adjustment can streamline the process of getting treatment to those who need it. Following are examples of two states that have passed legislation to address these administrative barriers.

EXAMPLES OF STATES WITH STRENGTHENED PRESCRIBING RULES

Colorado: To help navigate the challenges related to the state's law requiring names on prescription labels, the Colorado Pharmacy Board issued a statement in 2007 that created special standards for prescription labeling in the case of EPT. The resolution included using the patient's name on the prescription followed by the word "partner" when the partner's name is not provided.²⁵

Michigan: Michigan's public health code includes clear guidance on writing and recording prescriptions for partners, which eliminates confusing barriers that can prevent or delay treatment. First, the code instructs providers to document the partner's prescription in the patient's medical record and to "distinguish between prescription drugs dispensed to the patient, prescription drugs prescribed for the patient, [or] prescription drugs dispensed or prescribed for expedited partner therapy."²⁶ Second, a subsection of the code includes clear guidelines for carrying out EPT, and clearly states that if the partner's identifying information is unknown, providers should "prescribe the therapy in the name of 'expedited partner therapy.'"²⁷

The 2015 PolicyLab study found that, regardless of the legal status of EPT in their state, some of the other most commonly cited reasons for provider hesitancy about the practice of EPT were the missed opportunity to counsel partners (82%), difficulty ensuring the delivery of medication (79%) and concern that the partner might not understand potential adverse effects of the medication (77%).³

EPT requires a health care provider to dispense or prescribe medication for a person he or she has never met. Some providers raise the point that **treatment without an in-person clinical evaluation is a missed opportunity to counsel partners** about follow-up evaluation, screening for other STIs and healthy behaviors to reduce the risk of future infection. There is additional concern when providing medication for female partners of men infected with chlamydia or gonorrhea due to the risk of PID in women, which EPT medication does not adequately treat.

However, providers should not discount EPT even with the concern about untreated PID. While examining every partner of every patient with chlamydia or gonorrhea before treatment would be ideal, it is not always possible. The EPT treatment for uncomplicated infections is effective for most people who take it, and it can help to prevent more potential cases of PID from developing.

Providers also note the **difficulty ensuring that the patient will deliver the medication or prescription to his or her partner(s) and that the partner will accept the treatment**. The patient or partner could also resume sex before treatment can take effect or initiate sex with a new partner who is infected.⁷ While valid concerns, these uncertainties about treatment compliance exist for essentially all other treatments, including the standard patient referral practice. Given that some research suggests the potential for greater compliance with EPT than patient referral,¹⁵ providers should address

possible reasons for noncompliance with the patient and partner(s) to help improve the practice of EPT and increase the likelihood of positive outcomes.

Finally, providers could be concerned that **the partner might have an adverse reaction to the medication** that could have been prevented if he or she had been seen for a clinical evaluation prior to its prescription. While no medical intervention is 100% risk free, significant side effects from the currently recommended treatments used with EPT are extremely rare. This risk should be weighed against the risk of recurrent infection in the diagnosed patient due to resumed sex with an untreated partner and the potential spread of the infection to others.

SOLUTIONS

Provider concerns about the quality of EPT as a treatment and prevention method can be alleviated by addressing the knowledge gap around EPT's practice and efficacy. Ways to address provider concerns and minimize risk associated with EPT include the following strategies:

Health care educators should improve education and training on EPT for health care providers at all levels. Educational experiences about STI diagnosis, treatment and prevention are incomplete if they do not include adequate information about the practice of EPT. Existing medical school curricula, continuing medical education (CME) options and resources for clinical educators around STIs in both adolescent and adult populations should be expanded to cover the option of EPT, including its benefits, limitations and logistics of incorporating it into existing treatment practices. Lessons and training modules focused solely on EPT should also be developed to address legal, ethical and clinical concerns about the practice. CME about EPT for supervising physicians involved in residency programs could also increase comfort with the practice and improve medical training.²¹

OPPORTUNITIES TO IMPROVE AVAILABLE HEALTH CARE EDUCATION AND TRAINING MATERIALS

Training modules about the treatment and prevention of STIs, including chlamydia and gonorrhea, are available through the CDC for both self-study CME and for clinical educators to use in the classroom. However, the resources specific to chlamydia mention EPT only briefly and indicate that it is an option in some jurisdictions, but do not provide details or logistics about proper use. The resources specific to gonorrhea do not mention the practice by name and simply state “delivery of antibiotic therapy by the patient to their partners is an option.”^{29,30} Enhancing the materials available through these existing resources to include more substantial information about the use of EPT would capture a missed educational opportunity and could increase awareness and acceptance of the practice among providers.

Providers should distribute informational materials to every patient receiving EPT to address concerns regarding potential risks related to treatment without prior evaluation. In addition to the prescription or medication, materials that patients deliver to their partners should include⁷:

- Instructions for taking the medicine and the amount of time to wait before it is safe to resume sex
- A strong recommendation to seek follow-up testing and treatment. The materials should place particular emphasis on follow-up testing for women because of the risk of PID, and for gonorrhea infections due to the change in recommended treatment that includes an injection, which cannot be provided through EPT.
- Referral to a location that will provide free evaluation

- Warnings about possible medication side effects and symptoms
- A number to call if the patient has any questions or problems with the treatment

Providers should include the actual medication rather than the prescription, when possible, to increase the likelihood of acceptance. A trip to the pharmacy or the cost to fill the prescription may be an additional barrier to partner treatment. When a provider must use a prescription, he or she should include an order for the pharmacist to screen for drug allergies and/or provide counseling when it is filled to alleviate concerns about adverse effects and missed opportunity to counsel.

4

BARRIER: ADOLESCENTS PRESENT UNIQUE CHALLENGES TO PROVIDERS.

The PolicyLab study found that approximately one in four providers felt they might need parental consent in order to offer EPT to their minor patients,³ which is typically not legally the case for minors seeking any STI-related services. This concern is an additional challenge related to unclear state laws and policies regarding the practice of EPT, and is further complicated by the prospect of providing medication to a minor partner without first evaluating them and without receiving their parent’s permission.

A second major concern among providers surrounds cases that involve minor patients with older partners.

Although they vary, every state has mandatory reporting requirements for incidents of statutory rape. Even if a minor consents to sexual activity with an older partner, health care providers must report it if the ages and age differences constitute statutory rape based on criminal law in that state.⁷ The reveal of an older partner’s name and age for the purposes of writing a prescription in states that require such information could trigger mandatory reporting of the sexual activity, which could serve as a deterrent for minor patients to seek treatment altogether.



SOLUTIONS

Unlike laws regarding the permissibility of EPT, laws regarding statutory rape and minor consent for treatment are very clear. Every state allows minors—though ages vary by state—to access STI services without parental consent.³¹ Similarly, every state has laws regarding the age and age differences at which sexual activity is considered to be statutory rape and require action on the part of the health care provider.³² Providers must comply with the laws of their state while also working to promote access to care for their minor adolescent patients. The following strategies could help to ensure access to EPT for minors seeking treatment for themselves and their partners.

State health departments should add or clarify the inclusion of EPT within their minor consent laws.

It may not always be clear that accepting treatment from a partner is the same as consenting to a health service as defined in some state laws. For instance, Pennsylvania's Minors' Consent Act states that "A minor can consent to testing for any venereal or sexually transmitted disease (STD), and medical and health services to treat the disease. These include but are not limited to HIV and AIDS, chlamydia, gonorrhea, and syphilis."³³ The Pennsylvania Department of Health could help

providers avoid confusion about using EPT for minors by issuing a bulletin clarifying that EPT fits within this act.

Health care educators should ensure providers are well-informed about relevant state laws, including the age at which minors can seek STI services on their own, the age of consent for sexual activity and the age differentials that meet criteria for statutory rape. As described on page 9, there are multiple opportunities for provider education, including medical school curricula, continuing medical education (CME) options and resources for clinical educators around STIs in both adolescent and adult populations. As these forums are expanded to include information about EPT, health care educators should also include education around consent laws.

Medical institutions should establish clear clinical protocols for providing sexual health services to minors to ensure adherence to state laws and standardize expectations for both the patients and providers. Most institutions have clear guidelines around child abuse mandated reporting, including for sexual abuse or assault. When available, social work colleagues can serve as resources, as can city, county and state child protection agencies.

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The aim of PolicyLab at Children's Hospital of Philadelphia is to achieve optimal child health and well-being by informing program and policy changes through interdisciplinary research.

PolicyLab develops evidence-based solutions for the most challenging health-related issues affecting children. We partner with numerous stakeholders in traditional health care and other community locations to identify the programs, practices, and policies that support the best outcomes for children and their families. PolicyLab disseminates its findings beyond research and academic communities as part of its commitment to transform evidence to action.