

Position paper

Expedited Partner Therapy for Adolescents Diagnosed with Chlamydia or Gonorrhea: A Position Paper of the Society for Adolescent Medicine

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Chlamydia and gonorrhea, the most frequently reported sexually transmitted infections (STIs), present substantial public health challenges among adolescents. Although these infections are easily treated with antibiotics, many adolescents are reinfected within 3–6 months, usually because their partners remain untreated. The standard approaches to notifying and treating a partner of an STI-infected patient are patient referral, whereby the patient notifies his/her partners to seek care, and provider referral, whereby the provider or public health disease intervention specialist notifies the partner and directs him/her toward treatment. These methods rely on the accuracy of the disclosed partner information as well as other limitations, such as compliance and staffing resources. Another approach to partner notification is expedited partner therapy (EPT), treating sex partners without requiring a prior clinical evaluation. In randomized trials, EPT has reduced the rates of persistent or recurrent gonorrhea and chlamydia infection; however, its routine use is limited by concerns related to liability, cost, compliance, and missed opportunities for prevention counseling. The Society for Adolescent Medicine (SAM) recommends that providers who care for adolescents should do the following: use EPT as an option for STI care among chlamydia- or gonorrhea-infected heterosexual males and females who are unlikely or unable to otherwise receive treatment; through SAM and AAP chapters, collaborate with policy makers to remove EPT legal barriers and facilitate reimbursement; and collaborate with health departments for implementation assistance.

Positions

The Society for Adolescent Medicine (SAM) and the American Academy of Pediatrics (AAP) endorse the following positions:

- 1) Providers who care for adolescents should use expedited partner therapy (EPT) as an option for sexually transmitted infection (STI) care among partners exposed

within the past 60 days to heterosexual males and females with chlamydia or gonorrhea infections when other partner management strategies, using in-person evaluation and treatment, are impractical or unsuccessful.

- a. SAM and AAP chapters can assist pediatricians and other health care providers to become familiar with legal issues concerning implementation of EPT in their state. Information is available at the following: (1) the Centers for Disease Control and Prevention (CDC) National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Web site, at www.cdc.gov/std/ept/legal [1]; (2) The Centers for Law and the Public's Health EPT Web site, at www.publichealthlaw.net/Projects/EPT.php [2]; (3) the AAP Division of State Government Affairs at e-mail stgov@aap.org or by telephone at (847) 434-7799; or (4) the American Medical Association (AMA) Web site at <http://www.ama-assn.org/ama1/pub/upload/mm/471/ceja6.doc> [3].
 - b. As part of an EPT program, providers should include educational and STI counseling materials detailing partner medication indication, instructions, and warnings; referral to a local testing center for complete STI evaluation, and instructions to abstain from intercourse for 7 days after treatment. For examples, see CDC EPT Resources from States at www.cdc.gov/std/ept [4].
 - c. SAM and AAP chapters can reference AMA [3,5] and CDC [6] supportive EPT policies.
 - d. Additional information may be found at the CDC Web site www.cdc.gov/std/ept [4].
- 2) Pediatricians and other health care providers should work with SAM and AAP chapters to modify existing laws or regulations regarding EPT in jurisdictions where laws may impede EPT implementation. This can be accomplished by working through SAM and AAP chapters to coordinate efforts to examine and

clarify existing laws and, where needed, to seek legal reforms. For example, as has already occurred in some states, a law that precludes prescribing drugs absent a physician–patient relationship can be modified or interpreted to allow the provision of treatment for partners of patients with STIs when this treatment is in accordance with the EPT guidelines and protocol published by the state health department [7]. Similarly, specific statutory or regulatory provisions that authorize physicians to practice EPT for chlamydia or gonorrhea infections only may be promulgated [8].

- 3) Providers should work with SAM and AAP chapters and health departments for assistance with local EPT implementation. EPT guidelines should be customized by each state and jurisdiction to address their needs, and should be developed in a collaborative effort between SAM and AAP chapters and health departments. For example, at least one health department was able to work with community providers to conduct EPT for their referred patients [9–11].
 - a. Providers and health departments can also work collaboratively by referring patients to publicly funded sexually transmitted disease (STD) clinics to fill EPT prescriptions without examinations.
 - b. Health care providers, SAM and AAP chapters, and health departments must work together to develop local protocols and procedures to standardize EPT in each state and jurisdiction. This includes addressing how records will be kept for patients not examined, payment for EPT prescriptions, and confidential billing. Health departments and SAM and AAP chapters can provide subsequent training in these procedures.
 - c. Providers can work with health departments to establish a system for reporting adverse events associated with EPT, such as a state-level EPT adverse reactions hotline e-mail address and telephone number [3,12].
- 4) Because partner counseling and administrative tasks associated with EPT use provider time, providers should work through SAM and AAP chapters to establish codes or strategies to confidentially bill for STI counseling that is needed to implement EPT.
- 5) Researchers must evaluate EPT effectiveness among men who have sex with men (MSM) and among women who have sex with women (WSW), as these populations are also at high-risk for STI reinfection.

Background Information

Chlamydia and gonorrhea—the most frequently reported STIs—are substantial public health challenges among adolescents and young adults. According to prevalence statistics based on the National Health and Nutrition Examination Survey (NHANES, 1999–2002), a periodic health

survey of a nationally representative sample of persons living in the United States, chlamydia and gonorrhea prevalence rates among 14–19-year-olds are 3.4% and 0.61%, respectively [13]. The National Longitudinal Study of Adolescent Health (Add Health) cohort, a sampling of young adults ages 18–26 years, demonstrated similar results, reporting rates of 4.9% for chlamydia and 0.43% for gonorrhea [14].

Although chlamydia is easily treated with a single-dose antibiotic regimen, many adolescents are reinfected within 3–6 months. Studies have found between 14% and 26% of adolescent and young adult women to be reinfected with chlamydia within 12 months after their initial infection [15–17]. Two prominent risk factors emerge: age and untreated partners. In a longitudinal study of 3,860 sexually active females aged 12–60 years tested for *C. trachomatis* by polymerase chain reaction in Baltimore City clinics over 33 months, among females <25 years of age, the chlamydia incidence rate was 20.3 cases per 1,000 person-months. This rate was substantially higher than the 3.6 cases per 1000 person-months rate among females ≥25 years [18]. The relative risk of having a repeat positive chlamydia test result was 8.9 (95% CI = 5.6–14.3) for females <25 years relative to females >25 years [18]. In a multicenter study of young women treated for uncomplicated *C. trachomatis* infection and retested by urine ligase chain reaction (LCx, Abbott Laboratories, Chicago, IL) at 1 and 4 months after treatment, although of these women most believed that their partners had been treated, reinfection was twice as likely among females who had resumed sexual activity with their partners [15]. Another study showed that among 15–19-year-old females, independent reinfection risk factors included initial gonorrhea infection and reporting two or more partners in the previous 3 months [19]. These data have led many experts to recommend offering a test-of-reinfection to those testing positive 3–4 months after the initial infection. However, this recommendation does not address the main underlying cause—reinfections resulting from continued contact with an infected partner.

There are multiple avenues for notifying and treating the partner of a patient with a documented STI: patient referral (the patient notifies his/her partners to seek care); provider referral (the provider, who is often, but not always, a public health disease intervention specialist, notifies the partner and directs him/her toward treatment); and contract referral (health service personnel contact those partners who do not visit the health service by an agreed date). Each approach relies on accurate identification of partners. Perhaps most widely used, least costly, and yet least effective, is patient referral. In a survey addressing STI management practices of a random national sample of 7,300 physicians practicing in five medical specialties, approximately 80% of respondents reported routinely counseling gonorrhea- or chlamydia-infected patients to refer their partners for evaluation and treatment [20]. A sample of 241 patients aged 13–20 years who were counseled to notify their partners after being diagnosed with gonorrhea, chlamydia, trichomonas, or nongonococcal urethritis at an STD or primary care adolescent clinic reported notifying only

59% (164/279) of partners [21]. Provider referral is more effective than patient referral but is often limited by partner identifying information and partner accessibility as well as compliance and available financial and staffing resources. In a nongonococcal urethritis partner notification trial, provider referral resulted in more partners receiving treatment (0.72 contacts per infected patient) compared with patient referrals (0.18 contacts per infected patient) [22]. Using a labor-intensive approach, a gonorrhea and chlamydia case field follow-up evaluation found that by locating and treating partners identified by the index patient, STD Program field staff were able to track 82% of the partners identified [23]. Although optimal partner management involves attempting to bring the partner to clinical care for evaluation, counseling, testing, and treatment, few health departments or medical providers have the resources to contact all persons diagnosed with chlamydia or gonorrhea to identify and refer all sex partners for evaluation and treatment [20,24].

Another approach to the partner notification challenge is expedited partner therapy (EPT), the practice of treating the sex partners of STI-infected persons without requiring the partners' prior clinical evaluation. EPT is usually practiced as patient-delivered partner therapy, whereby the patient delivers medication or a prescription to the partner. In a study of 14–25-year-old females, 89% preferred to deliver medication to their partner and 7% chose to refer their partner for treatment [25]. Among chlamydia-infected 14–34-year-old females, there was a non-statistically significant trend for reduced reinfection rates among patients enrolled in the EPT arm compared with the patient referral arm. EPT was at least comparable to patient referral in lowering reinfection rates, and no adverse effects were reported [26]. Among men and women infected with gonorrhea and/or chlamydia, compared with standard partner referral strategies, EPT reduced the proportion of repeat positive gonorrhea tests (3% vs. 11%; $p < 0.01$) and the proportion of repeat positive gonorrhea or chlamydia tests (10% vs. 13%; $p = 0.04$) [10]. There was also a trend for a lower rate of repeat chlamydia-only-positive tests among patients enrolled in the EPT arm (11%) compared with those in the control arm (13%; $p = 0.17$). In a recent meta-analysis, EPT was successful in reducing risk of repeat positive chlamydia or gonorrhea tests (summary risk ratio = 0.73, 95% CI = 0.57–0.93) [24]. There are limited data on EPT effectiveness to prevent recurrent chlamydia among MSM or WSW. Because male sexual contacts of gonorrhea- or chlamydia-infected MSM are more likely to have human immunodeficiency virus (HIV), syphilis, or other STI co-infection, EPT for male partners of MSM requires further study [27].

Statement of the Problem

Although EPT is an effective and acceptable technique to decrease gonorrhea or chlamydia reinfection rates, its use in routine clinical practice is limited by complex barriers. These obstacles include the risk of adverse drug effects resulting from prescribing a medication without prior partner evalua-

tion, EPT legal status and liability concerns, statutory rape reporting requirements, cost issues, administrative challenges of recording prescribed medications without a medical record, missed opportunities for STI prevention counseling and partner evaluation for sequelae such as pelvic inflammatory disease or STI co-infection, and both index case and partner compliance issues. Health care providers should collaborate with SAM and AAP chapters and health departments to address these obstacles and to implement guidelines for EPT use in their jurisdictions.

Adverse drug effects

Adverse drug and allergic reactions in sexual partners treated without direct medical supervision are potential problems for all medications likely to be used for EPT. However, serious adverse reactions are rare with recommended chlamydia and gonorrhea treatment regimens such as doxycycline, azithromycin and cefixime [28,29]. Transient gastrointestinal side effects are more common but rarely result in severe morbidity. Educational information accompanying the prescription regarding possible drug side effects and providing partners with a phone number to call if they experience severe adverse effects are strategies that should be used to decrease adverse reaction risk. In addition, an order can be placed on the prescription for the pharmacist to screen for drug allergies before dispensing medications.

Since quinolone-resistant *Neisseria gonorrhoeae* has emerged throughout much of the United States, cephalosporins have become the only first-line, single-dose treatment option for *N. gonorrhoeae* [30]. Providers may be apprehensive about dispensing cephalosporins to unexamined partners based on the belief that penicillin-allergic patients may experience an adverse drug reaction to cephalosporins. Although first- and second-generation cephalosporin package inserts suggest a 10% cross-sensitivity risk as a possible contraindication to cephalosporin use among penicillin-allergic patients, a recent review of cephalosporin use in penicillin-allergic patients found that there is no evidence of an increased risk of anaphylaxis with second- and third-generation cephalosporins that are used to treat *N. gonorrhoeae* among penicillin-allergic patients [31]. In addition, anaphylaxis with cephalosporins is a rare event [31].

Legal status of EPT

CDC and legal scholars at The Centers for Law and the Public's Health at Johns Hopkins and Georgetown Universities examining state laws have concluded that only a few jurisdictions (11 at the time of this manuscript writing) have laws that prohibit the practice of EPT [32]. In fact, the majority (approximately 80%) of the 52 U.S. states and territories studied by CDC and the Centers either expressly permit EPT (15 jurisdictions) or may potentially allow its practice (24 jurisdictions) [1,6,32]. However, in a number of jurisdictions where EPT is potentially allowed, its legality may be

questioned because (1) specific laws to authorize, endorse, or support EPT are absent; or (2) existing laws are contradictory or insufficient to suggest that EPT is specifically allowed [32]. Resources for more information regarding EPT laws in a particular state include the following: (1) the CDC Web site “Legal Status of Expedited Partner Therapy” at www.cdc.gov/std/ept/legal/ [1]; (2) The Centers for Law and the Public’s Health EPT Web site, “Legal Assessment Concerning Expedited Partner Therapies” at www.publichealthlaw.net/Projects/EPT.php [2]; (3) the AAP Division of State Government Affairs at the e-mail address stgov@aap.org or at the telephone number (847) 434-7799; or (4) the AMA Web site <http://www.ama-assn.org/ama1/pub/upload/mm/471/cej6.doc> [3].

Uncertainty and misperceptions surrounding the legal status of EPT extend beyond practicing physicians. In 2003, medical and pharmacy board directors in all 50 states were surveyed by Golden et al to determine their perceptions regarding EPT legal status. Of the 74 completed surveys (37 medical and 37 pharmacy board respondents), five medical and four pharmacy board respondents indicated that EPT was legal in their state. Although at least one respondent from seven states indicated that EPT was legal, in three of these states the medical and pharmacy board respondents disagreed. At the time that the paper was published in February 2005, the four states with agreeing respondents were the only states with clearly defined laws permitting EPT. Respondents from boards in the remaining states were under the impression that EPT was illegal (64%), believed the laws to be vague (13%), or believed that the legal status was unknown (15%). In addition, the majority of respondents (52% of medical board and 55% of pharmacy board directors) did not know whether legal action would be taken against a practitioner who practiced EPT [33]. Responses in the Golden et al study were based on board members’ *perceived* illegalities rather than actual legal premises, further demonstrating medical professionals’ uncertainty and misperceptions regarding EPT legal status.

Liability concerns

Health care providers may *perceive* a substantial legal liability risk as a result of prescribing or dispensing antibiotics to their patient’s sexual partners to prevent gonorrhea or chlamydia reinfection without a prior examination of those partners. However, perceptions may not match reality. Because a health care provider’s duty of care is to prevent disease, in states in which EPT is legal, a provider would not likely be considered negligent for practicing EPT when indicated. On the contrary, in the case of a provider neglecting to offer EPT and the patient consequently developing multiple reinfections and subsequently chronic pelvic pain, infertility, or other sequelae, that provider could be found liable for negligence in failing to practice EPT.

Major national medical organizations (AMA [3,5] and CDC [6]) have published guidelines recommending EPT

use when indicated to prevent reinfection by sexual partners who are unlikely or unable to otherwise receive treatment. In addition, the American Bar Association supports the guidelines set forth by the CDC and recommends the removal of legal barriers hindering routine EPT practice [34]. In cases of medical liability, legal authorities will review these medical recommendations to determine whether EPT is practiced in a manner that is consistent with these guidelines. In a litigious medical environment, providing any medical therapy to a patient who has not been evaluated or examined could be considered a medical liability risk for the treating provider. Nevertheless, it should be noted that, in EPT programs in which adverse events have been monitored since 2001, no drug-related adverse effects or lawsuits arising from this type of care have been documented [10,12,26].

There are clearly other precedents for cases in which treatment is offered without a prior medical examination. For example, close contacts to meningococemia are routinely prescribed prophylaxis antibiotics without a clinical evaluation [35]. Influenza vaccine is administered to persons without a prior medical examination. In these situations in which prescription medication is provided to exposed or at-risk persons to prevent illness, health care providers cannot be considered negligent [32].

Statutory rape reporting

Legal requirements to report sexual activity involving a minor present an additional potential barrier to practicing EPT with adolescents. Every state has criminal laws that impose penalties for certain categories of sexual acts with a minor, even if the minor has consented. In addition, every state requires the reporting of some forms of sexual assault or sexual abuse; and sometimes the child abuse reporting laws incorporate some or all of the acts prohibited by the criminal laws. There is little uniformity among these laws across states, with variations in the age of consent, the sexual acts that are considered to be illegal, the sexual acts that are required to be reported, and the specific age difference between a minor and a partner that triggers a reporting obligation. EPT may require disclosing a partner’s name and age to dispense medications or to write a prescription, which could trigger mandatory reporting of the case. This could have unintended effects such as reducing the likelihood of minors’ willingness to seek medical care or providers’ willingness to use EPT. Providers need to be aware of their local jurisdictions’ reporting requirements and need to comply with them. It is also important, however, for providers to take whatever steps they can to achieve a balance that promotes access to care and reduces the STI burden in their adolescent patients while also ensuring compliance with reporting requirements [36]. In addition, providers must consider the vulnerabilities of younger adolescents with regard to predatory sexual behavior. This balance can be accomplished by establishing clinical protocols and working

closely with local jurisdictions on their legal mandated reporting requirements.

Cost issues

Challenges facing EPT implementation include the cost of the additional medication and reimbursement for time spent implementing EPT. Currently, there are no billing codes to cover expenses related to extra medication or counseling time for sexual partners. In addition, because a substantial number of adolescents and young adults are uninsured, the reimbursement opportunities for partner services are tenuous [6,37]. Providers can develop a relationship with the local STD clinic to develop a strategy for treating all partners, regardless of insurance status.

Administrative challenges

A major challenge for providers is to determine how to record the medication dispensation or prescriptions provided to patients who are not directly under their care. If medication dispensation is officially construed as part of the index patient's care, then medication or prescription dispensation to the partner may be recorded as part of the index patient's medical record. In most states, providers are legally required to maintain medical records for all patients for whom they prescribe medication. Providers may need to develop a medical record process to document care for partners who have never been examined in their office.

Because treating sexual partners of STI-infected patients is both a personal and public health intervention, EPT should be a collaborative effort between community providers, the local health department, and pharmacies. One such model in King County, Washington, involved an intricate network between community providers, the health department, the local medical society, and pharmacies, with the health department taking the lead administrative role. The health department assumed the responsibilities of patient care as well as the partner notification. In administrative terms, this entailed a record of participating providers and their contact information, a list of participating pharmacies and a running total for their medication inventory, plus a record of funds paid for dispensing fees. This innovative system proved to be an effective means of delivering treatment to infected partners, with 93% of contacted patients agreeing to disclose the infection to their partner(s) and 76% of those accepting the offer of free medication for their partner(s) [11]. After the King County health department expanded this program by promoting providers' use of a publicly financed EPT program and using STI case-report forms to triage selected patients to receive partner notification assistance, the proportion of cases of gonorrhea or chlamydia infection whose partners were treated increased from 39% to 65% [9]. However, this model is extremely complex, relies on multidisciplinary cooperation and robust health department funding, and may be difficult to replicate in other communities.

Missed care opportunity

Persons exposed to a STI are at elevated risk for other STI or HIV co-infections [27]. After receiving medication through EPT, there may be less incentive for an asymptomatic contact to obtain follow-up for a complete medical evaluation. Counseling materials accompanying the prescription or dispensed medication should encourage partners to receive complete STI evaluations despite receiving treatment [3]. The risk of concomitant infections that are not treated by the dispensed medication should be clearly stated, and information for local testing sites should be provided. Counseling materials should also stress the importance of condom use to decrease the risk of subsequent infections as well as abstinence for 7 days after receiving treatment and 7 days after partner(s) treatment. Also, female partners who have pelvic inflammatory disease may mistakenly believe that they are fully treated by the medications they receive for uncomplicated STIs via EPT. Counseling materials should recommend that females with abdominal pain seek medical evaluation and care immediately. Although the likelihood that exposed sexual partners at high STI risk will receive any prevention counseling is unknown, receiving EPT may not alter that likelihood. In addition, the pharmacist may provide counseling when the prescription is filled.

EPT compliance

Although EPT could substantially reduce STI reinfection rates among patients agreeing to this strategy, noncompliance by either the index case or the partner can diminish its effectiveness [26]. Index cases may fail to contact or give medication to all partners. Both index cases and partners may be noncompliant with their own treatment, may resume sex with their partner less than 7 days after both are treated, or may initiate sex with a new partner who is infected with an STI [26]. However, STI-exposed persons can be compliant with the tasks of EPT. In a community-wide study comparing EPT to standard partner referral for those individuals with gonorrhea or chlamydia in King County, Washington, only 7% of infected individuals asked for assistance in notifying a partner [11]. Furthermore, of those who agreed to use EPT, 84% successfully obtained the medication for their partner.

Summary

Adolescent gonorrhea and chlamydia rates continue to rise, whereas resources to prevent infection and reinfection are lacking. To interrupt the chain of transmission and to prevent reinfection after treatment, it is critical to treat the sex partners of STI-infected persons. Traditional partner notification strategies are fraught with resource and compliance challenges. EPT can improve providers' ability to treat hard-to-reach individuals who are now "falling through the cracks." CDC [6] and AMA [3,5] guidelines, endorsed by

the American Bar Association [34], recommend the use of EPT for the treatment of heterosexual partners of patients infected with gonorrhea or chlamydia when other partner management strategies using in-person evaluation and treatment are impractical or unsuccessful. However, similar to other mainstream public health interventions, multiple challenges to routine EPT implementation, such as legal concerns, administrative and cost issues, and missed opportunities for partner counseling and complete STI evaluation must be addressed. Providers who care for adolescents should practice EPT for chlamydia- or gonorrhea-infected heterosexual males and females whose partners are unlikely or unable to otherwise receive treatment. Providers should collaborate with policy makers through SAM and AAP chapters to remove EPT legal barriers and to facilitate reimbursement, and should collaborate with health departments for implementation assistance.

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