Expedited Partner Therapy: What Pharmacists and Technicians Should Know

Pharmacist Learning Objectives
At the end of this activity, participants should be able to distinguish the populations appropriate and not appropriate for Expedited Partner Therapy (EPT), select approved antibiotic regimens and alternatives for EPT, and express important patient and partner counseling points.

Pharmacy Technician Learning Objectives
At the end of this activity, participants should be able to distinguish the populations appropriate and not appropriate for Expedited Partner Therapy (EPT), select approved antibiotic regimens and alternatives for EPT, and identify signs of potential prescription fraud.

Knowledge-type Activity

Target Audience
This continuing education activity was designed for pharmacists and pharmacy technicians.

Faculty
Krista Lobkovich, Pharm.D. 2019 Candidate, Ferris State University College of Pharmacy
Lindsey Westerhof, Pharm.D., Ferris State University College of Pharmacy

Pre-Article Questions

1. Select the patient, if any, that is not appropriate to receive EPT. Assume the patient had sexual contact with a chlamydia or gonorrhea positive patient.
    a. 30YO male who had sexual contact with another male 45 days ago
    b. 26YO female who had sexual contact with another female 12 days ago
    c. 32YO male who had a one-night stand 55 days ago
    d. All of the above are appropriate for EPT
2. A 24YO male is positive for chlamydia. When asked by the Physician's Assistant (PA) if he has had any sexual partners recently he responds that he has had 3 partners in the last 90 days. Which of the following is correct?
    a. The patient and all 3 partners should receive prescriptions
    b. The patient and only the partners in the last 60 days should receive prescriptions
    c. The patient and only the partners in the last 30 days should receive prescriptions
    d. The patient and the most recent partner should receive prescriptions
3. A 32YO female brings two prescriptions to your pharmacy. One for herself and the other for a sexual partner she had. While looking at the prescriptions you notice that there is no information for the partner. The proper course of action is to refuse to fill the prescription.
    a. True
    b. False
4. EPT is legal in all 50 states and Puerto Rico.
    a. True
    b. False
5. Which of the following are examples of potential prescription fraud in regards to EPT?
    a. Doubling the medication quantity
    b. Writing for refills
    c. Doubling the dosing frequency and quantity
    d. All of the above are examples of potential prescription fraud.

Rates of sexually transmitted diseases (STDs), especially chlamydia and gonorrhea, in Michigan continue to soar despite continuous improvements in reproductive and public health. Since 2015 Michigan has seen an 6.9% and 45.2% increase in the rates of chlamydia and gonorrhea, respectively[1,2,3]. It was estimated in 2013 that the United States spent approximately 16 billion dollars annually on STD treatment[4]. It is common for chlamydia and gonorrhea to go untreated, mainly because they can present without symptoms or as mild genital discomfort. For chlamydia, it is estimated that only 10% of men and 5 to 30% of females have symptoms[2]. Untreated chlamydia and gonorrhea infections can lead to serious health consequences, including pelvic inflammatory disease (PID), ectopic pregnancy, and infertility in both men and women[5,6]. Both chlamydia and gonorrhea are easily treatable, but are just as easy, if not easier, to spread. For the clinically diagnosed patient, termed the index patient, to be considered completely and properly treated, they and their recent sexual partners should be treated with the appropriate antibiotic regimen. The lack of partner treatment puts the index patient at risk for re-infection and plays a significant role in the increases in chlamydia and gonorrhea rates in Michigan.

Expedited partner therapy (EPT) is permissible in forty-one states, potentially allowable in seven states, and prohibited in only two states[7]. Legalized in Michigan in January 2015, Expedited Partner Therapy is a proactive intervention that when used appropriately has the ability to coax chlamydia and gonorrhea rates to trend downwards[7]. EPT allows prescribers to proactively treat sexual partners of patients positively diagnosed with chlamydia and/or gonorrhea without physically seeing the partners in the clinic setting[5,6]. A positive diagnosis can be made using a urine culture, microscopy, or FDA-approved molecular test[6]. Michigan law also allows for EPT to be used based on a clinical diagnosis of chlamydia and/or gonorrhea[6].These partners are typically treated outside of the clinic setting because they are unlikely or unable to seek full clinical evaluation and treatment on their own[5,6]. The traditional standard of practice for treating sexual partners of positively diagnosed with either chlamydia, gonorrhea, or both is to have the index patient inform their partner(s) of their positive result and refer the partner to seek testing and treatment[9]. EPT is an alternative to that traditional method of partner treatment. There are several approaches to using EPT. The first approach, prescription-EPT, is the technique in which a provider will write a prescription for both the patient and the partner[9]. The next approach, medication-EPT, is the technique in which a provider will dispense the appropriate antibiotics for the index patient and their partner(s)[9].

Since EPT law and use is still young in Michigan and pharmacists may not be familiar with this the process, some may be hesitant at first. However, because of the excused liability and high rates of STDs in Michigan, community pharmacies are encouraged to adopt this practice. Pharmacists may also be hesitant because they may not be able to discuss the medications in person with the partner being treated. However, EPT law allows for liability to be excused except in cases of gross negligence[6]. Patients and partners are also provided with literature regarding their diagnosis and medications, which serves as a “take home pharmacist”. Pharmacists and pharmacy technicians can find these educational documents and literature on the Michigan Department of Health and Human Resources website. This information can be printed and attached to each prescription bag to ensure that the information reaches the

patient and/or partner. The patient education covers the most important counseling points that coincide with what a pharmacist should discuss while the patient or partner was present in the pharmacy.

While all patient populations are susceptible to chlamydia and gonorrhea, males and females between fifteen and twenty-four years of age are the most frequently impacted[5,6]. Males and females in this age range are the most vulnerable for multiple reasons, including social, behavioral, and physical reasons. These individuals are more likely to have multiple sexual partners, engage in unprotected sex, use drugs and/or alcohol at higher rates, and engage in risky behaviors while under the influence of drugs and/or alcohol[5,6]. Females in this age range are particularly susceptible to STDs due to their immature cervix[5,6]. However, this does not exclude other populations from being candidates for EPT. EPT inclusion criteria include partners of patients positively diagnosed with either chlamydia, gonorrhea, or both, partners of patients without positive diagnosis of either STD but have a high likelihood of infection or there is concern for loss of follow-up, and partners that are uninsured, have no primary care physician (PCP), have significant barriers to medical care, or are unwilling to seek medical care[6]. EPT exclusion criteria, however, is much more extensive. Exclusion to EPT include cases of suspected child abuse or sexual assault, situations in which the index patient's safety is questionable, partners with known antibiotic allergies, patients afflicted with STDs other than chlamydia and gonorrhea, and men who have sex with men (MSM) diagnosed with gonorrhea[6].. Table 1 lists the inclusion and exclusion criteria to decide whether or not an individual is appropriate for EPT.

Table1: Inclusion and Exclusion Criteria for EPT

Inclusion Criteria	**Exclusion Criteria**
- Partner of a patient positively diagnosed with chlamydia, gonorrhea, or both - Partner of a patient without positive diagnosis but has a high likelihood of infection based on clinical presentation - Partner of a patient in which there is concern for loss of follow-up - Partners with any of the following: a. Uninsured b. No PCP c. Significant barriers to medical care d. Unlikely to seek medical care	- Suspected child abuse or sexual assault - Situations in which the index patient's safety is questionable - Partners with known allergies to antibiotics - Patients co-infected with STDs other than chlamydia and gonorrhea - Men who have sex with men (MSM) diagnosed with gonorrhea

Although EPT is not considered a contraindication in pregnant women, it should be considered last line in this high-risk population. Pregnant sexual partners exposed to chlamydia

and/or gonorrhea should be strongly encouraged to seek comprehensive medical care including pregnancy and prenatal care[6,10]. If this proves to be difficult for the pregnant partner, EPT can still be used as the antibiotics prescribed are safe in pregnancy. However, doxycycline, an alternative antibiotic for chlamydia, should be avoided in pregnancy due to the potential for teratogenicity[11]. It is important to appropriately and successfully treat pregnant women since untreated gonorrhea and chlamydia can result in several complications for a newborn infant, including premature delivery, conjunctivitis, pneumonia, blindness, or joint infections[5]. Pregnant women who are treated for chlamydia should be retested three weeks and three months post-antibiotic therapy completion[5,6]. Due to the possibility of being potentially and unknowingly co-infected with other STDs, MSM should be referred for comprehensive medical3 evaluation to ensure complete and population appropriate care, including HIV and syphilis testing[6]. In 2017, 58% of primary and secondary syphilis cases were in the MSM population[12]. In 2014, 56% of established HIV cases and 70% of new HIV cases are in the MSM population[13]. Due to the possibility of being potentially and unknowingly co-infected with other STDs, MSM should be referred for comprehensive medical evaluation to ensure complete and population appropriate care, including HIV and syphilis testing[6]. Women who complain of low abdominal pain, pain during intercoruse, vomiting, and/or a fever should be seen immediately by a doctor to rule out PID. Severe or untreated PID can lead to infertility, pregnancy complications, and/or chronic pelvic pain[9]. Additionally, men who experience testicular swelling or pain (epididymitis) or a fever should referred to a doctor for immediate evaluation[10]. These are signs of a more serious and potentially complicated infection that requires more involved medical care.

STOP AND REFLECT

Your patient, a 32-year-old male, has a past medical history of hypertension and frequent urinary tract infections. He was seen by his PCP three days ago and was positively diagnosed with gonorrhea via a urine test. He reports that he is sexually active with multiple male partners and is HIV-negative. Are the sexual partners of your partner eligible for EPT?

Feedback

No. These sexual partners are not eligible for EPT even though the index patient reports being HIV-negative. Male index patients who report sexual contact with other males can be treated with appropriate antibiotic therapy. However, their sexual partners should be referred to seek their own medical evaluation due to the MSM population being considered a high-risk population. MSM partners should also be tested for HIV and syphilis.

The most recent STD guidelines published a list of suitable antibiotic regimens for chlamydia and gonorrhea. The guidelines recommend monotherapy with a single dose of azithromycin 1g by mouth once and dual therapy with ceftriaxone 250mg intramuscularly once plus azithromycin 1g by mouth once for the treatment of chlamydia and gonorrhea, respectively[14]. Alternative options listed by the guidelines are doxycycline 100mg by mouth twice daily for seven days and cefixime 400mg by mouth once plus azithromycin 1g by mouth once for chlamydia and gonorrhea, respectively. Antibiotic regimens legalized with EPT are azithromycin 1g by mouth once for chlamydia and azithromycin 1g by mouth once plus cefixime 400mg by mouth once for gonorrhea[6]. Therefore, partners being treated with EPT should only

be receiving prescriptions for azithromycin or cefixime rather than the guideline recommended ceftriaxone. Table 2 illustrates the appropriate EPT regimens for both chlamydia and gonorrhea.

Table 2: Approved Antibiotic Regimens for EPT

Chlamydia EPT Regimen	**Gonorrhea EPT Regimen**
Azithromycin 1g PO once	Cefixime 400mg PO once **plus** Azithromycin 1g PO once

Antibiotic resistance is a serious concern for healthcare professionals and patients alike. However, there is no evidence that the use of EPT results in an increase in antibiotic resistance[6]. In the case of pharyngeal gonorrheal infection it has been observed that oral cephalosporins, like cefixime, are less effective at eliminating the infection. In cases where partners are behaviorally at risk for pharyngeal gonorrhea, EPT should not be offered and should be encouraged to seek medical evaluation in order to receive the more appropriate antibiotic choice, intramuscular ceftriaxone[6,14,15]. Gonorrhea infections also exhibit geographic variation in resistance, therefore antibiotic surveillance is crucial for guiding therapy recommendations[2]. At this time there is no significant resistance of gonorrhea to ceftriaxone[2]. Furthermore, even if azithromycin was used to treat every chlamydia case over the course of one year, it would increase the overall azithromycin use by less than 5%, making EPT an insignificant factor in azithromycin resistance[6].

Prescriptions for EPT may come by way of phone, electronic, or paper media. Prescriptions for the partner(s) can be legally prescribed with or without the partner demographic or insurance information. Therefore, receiving a prescription without partner identifiers, such as full name and date of birth, is not grounds for a pharmacy to refuse to accept or fill an EPT prescription. Prescriptions without partner identifiers will have the name listed as “Expedited Partner Therapy” and the date of birth will be January 1st of the current calendar year (e.g. 01/01/2019). Under the EPT protocol this is considered a valid prescription and should be filled and processed as one. Prescriptions with partner information should be filled out with the partner’s full name (e.g. John Doe) and correct date of birth (e.g. 07/02/1985). The process of billing the prescription does differ between the two. If there is no partner identification then the prescription should be billed as cash or through a discount card. On the other hand, if there is partner identification then the prescription should be billed through the partner’s insurance if they are enrolled in a prescription drug coverage program. If the partner does not have insurance then the prescription should be billed as cash or through a discount card. Additionally, pharmacists and pharmacy technicians are able to provide their local health departments as a resource for patients and/or partners who may have trouble affording their prescriptions. Table 3 describes the information that should be on the EPT prescription for the two possible scenarios for both chlamydia and gonorrhea.

Table 3: Required Prescription Information for Different EPT Situations

Situation	Information On Prescription
Chlamydia Prescriptions	
No partner information available	Name: Expedited Partner Therapy Date of birth: 01/01/2019 Medication: Azithromycin 1g x 1 dose
Partner information available	Name: John Doe Date of birth: 07/02/1985 Medication: Azithromycin 1g x 1 dose
Gonorrhea Prescriptions	
No partner information available	Name: Expedited Partner Therapy Date of birth: 01/01/2019 Medication: Cefixime 400mg x 1 dose **plus** Azithromycin 1g x 1 dose
Partner information available	Name: John Doe Date of birth: 07/02/1985 Medication: Cefixime 400mg x 1 dose **plus** Azithromycin 1g x 1 dose

As pharmacists and pharmacy technicians, it is important to recognize when treatments, therapies, and/or protocols are being used appropriately and inappropriately. When we recognize a potentially inappropriate regimen, we must do our due diligence and reach out to available resources and the provider, if necessary. EPT is not excluded from this best practice. It is important for pharmacists and pharmacy technicians to be able to recognize potential fraud as it relates to EPT. For example, if a prescription for chlamydia or gonorrhea is brought to the pharmacy with refills or the quantity to be dispensed is double than what is typical, those would be appropriate reasons to refuse or call the provider on the prescription. A 2012 study found that approximately 16% of providers wrote an EPT prescription for the partner under the index patient's name, which is considered prescription fraud[9]. Ordering refills and doubling the quantity are two additional examples of fraudulent behavior on the behalf of providers and is not appropriate EPT practice. It is important with EPT to be able to recognize when an antibiotic is being used for the indication EPT. The 1g dosage of azithromycin is specific to the treatment of STDs, but most importantly the treatment of chlamydia[16]. The most common regimens to achieve 1g of azithromycin is to dispense four 250mg or two 500mg tablets[16]. It is important to counsel the index patient and/or partner that they should take the entire 1g dose of azithromycin at the same time rather than dividing the dose into multiple doses throughout the day. The 400mg dose of cefixime treats more than just gonorrhea infections, however it is important to note the duration of treatment. The one-day treatment duration for cefixime is

specific to gonorrhea[17]. The pharmacist's ability to recognize these nuances can help them to better identify appropriate and inappropriate use of EPT.

STOP AND REFLECT

Your pharmacy technician approaches you with a written prescription for a regular patient. As you analyze the prescription you notice that the prescriber wrote the prescription for azithromycin 500mg tablets with the directions "take 4 tablets by mouth for one dose" with a quantity of four. When you talk to the patient they tell you that they tested positive for chlamydia and the doctor wrote them this prescription. Should you fill this prescription?

Feedback

No. The azithromycin dosage in this scenario is 2g which is two times the dosage for the treatment of chlamydia. You should contact the prescriber and inform them that the appropriate dosage for chlamydia treatment is 1g. If the prescriber is trying to treat an uninsured sexual partner through EPT, they should write a separate prescription for the partner to avoid prescription fraud. If the partner expressed concerns for affordability to the provider, you can suggest that the partner contact their local health department as they may be able to provide antibiotics free of charge.

Pharmacists also have the duty of counseling the patient and/or partner on how to be successful in treating their current infection, preventing re-infection, and preventing spread of the infection. Patients and partners should be instructed to abstain from sexual intercourse of any kind (oral, anal, vaginal) for seven days after taking their antibiotics to prevent the spread of unresolved infection[10]. Partaking in sexual intercourse prior to complete disease resolution can still allow for transmission of the infection to other sexual partners. Patients and partners should also be instructed to reach out to sexual partners from the last sixty days and inform them of their positive test results and to see a doctor in order to be tested for STDs, including HIV[10].

It is also important to counsel the patient and partner(s) on practicing safe sex. The only 100% reliable way to avoid STDs is to practice abstinence. Practicing safe sex also includes the correct and consistent use of condoms[10]. Condoms are very effective in preventing gonorrhea and chlamydia infections. If a patient or partner does not know how to use a condom, this is an appropriate time for the pharmacist to intervene, address gaps in knowledge, and demonstrate the correct use of a condom. Pharmacists can also provide locations that offer potentially free condoms, if cost is a barrier to condom use. Affordable or possibly free condoms are available at local Planned Parenthood clinics, health departments, community centers, and college health centers. Spermicides, another barrier method used for practicing safe sex, are not effective at preventing all STDs[18]. However, spermicides are useful for preventing gonorrhea infections in women but should not be used as the only preventative measure during a sexual encounter[18]. Spermicides are not recommended for use during anal intercourse. Frequent spermicide use can result in genital lesions and irritation and therefore are not recommended as first line methods to preventing STDs[18]. Another strategy for risk reduction includes limiting the number

of sexual partners by practicing long-term monogamy and seeing a doctor regularly for physical exams that include STD testing[10].

It is also important for pharmacists to discuss potential antibiotic side effects. The most commonly experienced side effects with the EPT antibiotics is a mild, upset stomach that resolves on its own and in a short period of time[10]. Gastrointestinal issues, especially loose stools, vomiting, and nausea, are much more frequent with the 1g single dose of azithromycin than with the more common and lower doses of azithromycin[16]. Pharmacists can counsel patients to take their antibiotic with food to avoid the mild, upset stomach. It has been observed that previously treated men and women have a higher rate of re-infection with chlamydia and/or gonorrhea. Pharmacists should also reiterate to both the patient and the partner the importance of following up with their provider three months post-treatment and being retested to ensure infection resolution[6]. In the event that the patient and/or partner cannot be re-evaluated in three months, it is appropriate to encourage them to be re-evaluated at their next clinic visit within twelve months following their initial treatment[6].

With the rates of gonorrhea and chlamydia rising, it is important for pharmacists and pharmacy technicians to identify their role in aiding in the success of EPT and help STD rates begin to trend downward. In a 2005 study, these partners who received EPT experienced 3% and 11% disease recurrence in regards to gonorrhea and chlamydia, respectively. While partners who received traditional STD treatment experienced 11% and 13% disease recurrence in regards to gonorrhea and chlamydia, respectively[19]. Pharmacists and pharmacy technicians are trusted and easily accessible to the community, making them excellent sources of positive change and progress. Having said that, pharmacists and pharmacy technicians play an important role in the public health world and can help EPT make a larger impact on the sexual health of the community.

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Post-Article Questions

1. Select the patient, if any, that is not appropriate to receive EPT. Assume the patient had sexual contact with a chlamydia or gonorrhea positive patient.
    a. 30YO male who had sexual contact with another male 45 days ago
    b. 26YO female who had sexual contact with another female 12 days ago
    c. 32YO male who had a one-night stand 55 days ago
    d. All of the above are appropriate for EPT
2. A 24YO male is positive for chlamydia. When asked by the Physician's Assistant (PA) if he has had any sexual partners recently he responds that he has had 3 partners in the last 90 days. Which of the following is correct?
    a. The patient and all 3 partners should receive prescriptions
    b. The patient and only the partners in the last 60 days should receive prescriptions
    c. The patient and only the partners in the last 30 days should receive prescriptions
    d. The patient and the most recent partner should receive prescriptions
3. A 32YO female brings two prescriptions to your pharmacy. One for herself and the other for a sexual partner she had. While looking at the prescriptions you notice that there is no information for the partner. The proper course of action is to refuse to fill the prescription.
    a. True
    b. False
4. EPT is legal in all 50 states and Puerto Rico.
    a. True
    b. False
5. Which of the following are examples of potential prescription fraud in regards to EPT?
    a. Doubling the medication quantity
    b. Writing for refills
    c. Doubling the dosing frequency and quantity
    d. All of the above are examples of potential prescription fraud.

Post-Article Question Answers

1. The correct answer is A. This patient falls into the category of men who have sex with men, or MSM. Since MSM are at a higher risk of being coinfected with other STDs, this patient would not be appropriate to receive EPT. This patient should refer his partner to seek a comprehensive medical evaluation with a healthcare professional to screen for other STDs, especially HIV and syphilis.
2. The correct answer is B. This patient discloses that he has had 3 partners in the last 90 days. Under EPT law all sexual partners within the last 60 days are eligible for EPT.
3. The correct answer is false. The law for EPT is written to allow pharmacies to fill prescriptions for anonymous sexual partners of patients diagnosed with chlamydia or gonorrhea. If a pharmacist receives a prescription with the name "John Doe" and date of birth "01/01/2019" rather than true partner identification it is a valid prescription under EPT law.
4. The correct answer is false. EPT is legal in 41 states, potentially allowable in 7 states and Puerto Rico, and prohibited in 2 states. EPT was legalized in Michigan in January 2015.
5. The correct answer is D. All of the above are examples of prescription fraud. Doubling the quantity, dosing frequency, or both would be inappropriate for EPT prescriptions as these medications do not have indications for either double dosing or frequency. It is also inappropriate for antibiotics to have refills, therefore receiving a prescription with refills would prompt a call to the provider.