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# **ETHICS CASE**

# Expedited Partner Therapy: Clinical Considerations and Public Health Explorations

Commentary by Barry DeCoster, PhD, Lisa Campo-Engelstein, PhD, and Hilary E. Fairbrother, MD, MPH

Dr. Eptor is facing Nick, an adolescent in the community emergency department (ED). Nick is 16, has been sexually active for about a year, has had three partners in the last six months, and has now noticed green penile discharge for about a week. Nick is otherwise healthy and has no other symptoms. Embarrassed about his symptoms, he drove alone for over two hours to Dr. Eptor's ED out of fear of being recognized. Based on Nick's clinical symptoms, Dr. Eptor is fairly confident of a diagnosis of *Neisseria gonorrhea* urethritis and prescribes 250 mg intramuscular (IM) ceftriaxone plus 1g azithromycin by mouth. He sends off Nick's specimen for Gram stain and culture.

Dr. Eptor is also concerned about Nick's partners. He recently overheard fellow physicians talk about prescribing a double dose of an antibiotic to cover a potential infection in a partner, something they called "expedited partner therapy." Dr. Eptor practices in a rural area and mostly deals with members of the local farming community. He has not seen an adolescent with a sexually transmitted infection (STI) in almost five years and generally feels uncomfortable working with this population of patients. Coincidentally, he is currently being sued for misdiagnosing acute coronary syndrome (ACS) as gastric reflux three months ago, so he is feeling uneasy and on edge about making a misstep.

Dr. Eptor struggles as he thinks about Nick and his three female partners. "How could I prescribe something to a person I have never met? What if one has an adverse reaction or doesn't respond to the medication? Is it ethically justifiable for me to prescribe ceftriaxone, an IM medication?" Dr. Eptor knows that resistance to gonorrhea treatment has been increasing but he doesn't know the specific resistance profile for the area where Nick lives.

After some reflection, Dr. Eptor also becomes concerned that if he doesn't provide Nick with additional prescriptions, Nick's potentially asymptomatic partners might not ever seek care and could develop complications. Dr. Eptor doesn't want to be responsible for missing an opportunity to treat a subclinical infection in a young woman and risk her developing pelvic inflammatory disease (PID), which could compromise her fertility. He wonders about the scope of his public health role in this case and isn't sure whether the

decision he makes will be compliant with his state's regulations and institution's guidelines and protected from a legal standpoint.

#### Commentary 1

#### by Barry DeCoster, PhD, and Lisa Campo-Engelstein, PhD

This case raises important ethical complexities, even in the relatively straightforward example of a sexually transmitted infection. Dr. Eptor has a clear duty to care for Nick, but this case raises ethical concerns about STI care as part of the broader scope of physicians' public health roles. Dr. Eptor knows that Nick's three female sexual partners are at a high risk of being infected. Does he have a duty to these women directly, even if they are not his patients? Do Dr. Eptor's duties to treat extend to the community at large?

#### **Goals of Care and Ethical Responsibilities**

These questions suggest different—possibly conflicting—goals of clinical bioethics and public health ethics. Clinical bioethics has traditionally focused on the ethical complexities at the micro level of primary care (i.e., the doctor-patient relationship) rather than at the macro level. Yet these dialogues are only partially helpful here for understanding what Dr. Eptor owes to Nick and Nick's sexual partners. Public health ethics can be defined as "the principles and values that help guide actions designed to promote health and prevent injury and disease in the population" [1]. One way public health ethics differs from clinical ethics, then, is by prompting physicians to think about the needs of populations, not just individual patients, as ethically relevant to their decisions. In other words, from a public health perspective, physicians need to think about the problems facing populations, including social determinants of health; to think about prevention in addition to treatments and cures; and to seek ethically defensible responses that improve the health and well-being of populations [2]. In this case, Dr. Eptor is considering not only Nick's health, but also the needs of his sexual partners. Dr. Eptor might consider expanding his goals of care to include not only Nick's partners, but also the greater rural community. Acknowledging this broader goal helps us to better frame the ethical questions that Dr. Eptor should consider.

Furthermore, although Dr. Eptor expresses discomfort about prescribing EPT, he might have a strong ethical obligation to do so, since male-to-female transmission of STIs is greater than female-to-male transmission [3]. Thus, Nick's female partners are at greater risk than if Dr. Eptor's patient were a female with male partners.

A challenge that Dr. Eptor faces in this case is the tension between the view that medicine's duties are only or primarily clinical and the view that medicine also has public health duties. On the one hand, Dr. Eptor has clear and immediate clinical duties to Nick to do what is in Nick's best interests. On the other hand, his duties, framed from a public health ethics perspective, suggest that his responsibilities extend to protecting the

health and well-being of other members of the community, some of whom would be Nick's sexual partners, the three women with whom he has recently had sex and who might be infected. Given that Dr. Eptor (likely) has not met these women, we can ask two important questions. First, what is the nature of Dr. Eptor's ethical obligations to these women? Second, what is the scope of his duty to reach out to and treat them? One response might be to say that Dr. Eptor has no duty except to his patient, Nick. Yet, even if we take this view, we must acknowledge that Nick faces a high likelihood of reinfection if he has sex again with any of these women before they are treated. So, Dr. Eptor's treatment of Nick's sexual partners could be an indirect way of providing *preventive* care to Nick [4, 5].

#### **Expedited Partner Therapy**

One way to handle this situation is via expedited partner therapy (EPT), in which a physician prescribes treatment for a patient's sexual partners without seeing them. If Dr. Eptor were to follow his colleagues' lead by prescribing a "double dose" or multiple doses of antibiotics, he would have to make sure that Nick understands that the additional pills are to be shared with his partners. Prescribing this double dose with the expectation that it is to be shared with a partner has a clinical history [6]. This kind of semi-clandestine approach to treatment via double dosing has been common historically, albeit "not traditionally condoned" [7]. This subterfuge becomes unnecessary if Dr. Eptor practices in a state that has legalized anonymous prescriptions via EPT [8]. In fact, only four states prohibit EPT [9]. In states where anonymous prescriptions via EPT are legal, Dr. Eptor could write a prescription to Nick directly and to multiple unnamed prescription recipients to whom Nick could deliver the antibiotic. The CDC recommends EPT for all sexual partners in the last 60 days [10]. This means EPT prescriptions can be written for as many partners as is appropriate. Dr. Eptor would have to discuss the timing of Nick's sexual activity to determine which of his partners should be treated via EPT. Once filled, the prescription would be accompanied with literature on safety and how to contact a pharmacist if any of the women were to have questions.

#### **Deciding Whether to Recommend EPT**

There are several elements Dr. Eptor needs to consider in deciding whether to recommend EPT for Nick's partners.

*Legal considerations.* States where EPT is legal vary as to which diseases can be treated on this model of care. In some states, like California [11], both chlamydia and gonorrhea may be treated via EPT; in other states, like New York [12], EPT can only be used to treat chlamydia. Clinicians thus have a responsibility to understand the legal status of EPT in the states in which they practice, which can be easily found on the CDC website [9].

*Is Nick reliable enough?* Because EPT requires explicit conversations about taboo subjects, such as sex in general and STIs in particular, Dr. Eptor and Nick will have to have a frank

discussion about whether Nick is prepared to take on the responsibilities of EPT. EPT is an appropriate alternative to the standard process of referring sexual partners to seek clinical attention, but it is not demanded of Nick. In this case, both Nick and Dr. Eptor must be reasonably certain that Nick is willing to and capable of contacting partners and of passing along both the medication and attached information.

Whether Dr. Eptor is comfortable prescribing EPT for Nick's sexual partners depends on whether he considers Nick a reliable messenger of risk information to the unnamed women. Here, it is important to remember that Nick is requesting EPT as a means for self-care and as a means of expressing some regard for his sexual partners. Perhaps he's also trying to maintain or even repair those relationships, particularly if any of Nick's partners feel angry or betrayed that he may have infected them with gonorrhea. If Nick is concerned enough to seek out and distribute the antibiotics, then perhaps he can also be relied upon by Dr. Eptor to convey risks and encourage follow-up care. If Nick has no real relationship with these women (say, a one-night stand) and cannot find them, then Dr. Eptor cannot rely on Nick to communicate risk information or to distribute the prescription.

As we have noted above, Dr. Eptor has a responsibility here to have a frank conversation with Nick, one in which the patient is supported given his discomfort, and to inquire about facets of the case that include not just Nick, but also what Nick knows about his partners. This effort will ultimately benefit both Nick and the women who possibly may be infected.

EPT is an effective tool meant to facilitate and improve treatment rates for STIs, and compliance of partners is high [4]. EPT, though, is not a magic bullet. Should Nick feel uncomfortable as a messenger for whatever reason, standard public health reporting systems remain the default.

*Does the threat of antibiotic resistance make EPT unsafe?* One important consideration is that an antibiotic-resistant strain of gonorrhea is on the rise [13], although Dr. Eptor is not sure if this is the case where Nick lives. In part, the threat posed by antibiotic resistance has shaped public health law [13, 14]: in some states, such as New York, EPT is legal only for chlamydia [15]. A possible concern is that without proper follow-up testing, resistant strains of gonorrhea will likely spread, possibly even among people who have been treated for it before. Certain antibiotics are not eligible for EPT because they are not available in pill form and must be administered by a health care professional via IM injection [4]. Thus, Nick is eligible for the IM injection for his treatment of gonorrhea, but it is not possible to treat Nick's sexual partners via IM injection without a clinical visit; the CDC recommends EPT via prescription of antibiotics in pill form for those unlikely or unable to receive clinical evaluation and treatment [13].

In this case, Dr. Eptor could reasonably counsel Nick about risks of antibiotic-resistant strains of gonorrhea and plan for Nick to return for follow-up screening. If Nick tests negative, then Nick's treatment—and presumably Nick's partners' treatment via EPT—can probably be considered successful. If Nick tests positive for a resistant strain of gonorrhea, then Dr. Eptor will have to prescribe a different (IM) antibiotic to treat Nick and suggest the same for his partners, who would need to see doctors to receive it.

*Obligations to Nick's partners.* But what does Dr. Eptor know about or owe to Nick's female sexual partners? One ethical concern is that these women may believe that they have successfully treated their gonorrhea and thus see no need to seek follow-up treatment. If their STIs persist, however, one risk is that they could infect others. Another risk is that they might develop serious complications—such as PID, which can lead to infertility or ectopic pregnancy [16]—as a result of having what could turn out to be an untreated, subclinical STI [16]. Such outcomes could be personally devastating for these women, and treating infertility via assisted reproductive technologies, for example, is frequently not covered by insurance [17]. This makes it all the more important for Dr. Eptor to prescribe for Nick's partners only if he is confident that Nick can be relied upon to convey information about the need for follow-up care.

*Recommendation*. Although the use of EPT raises numerous ethical concerns from clinical and public health ethics points of view, we argue that Dr. Eptor would be acting responsibly from clinical and public health ethics points of view in prescribing EPT to Nick and his three partners, assuming it is legal in the state where they reside. EPT could benefit not only Nick but also his partners by providing them with treatments for their potential infections that are convenient (i.e., not requiring a visit with a health care provider) and possibly cost-free (i.e., covered by Nick or another third-party payer). Furthermore, it would enable Nick to take responsibility for his own health and the health of his sexual partners. Lastly, EPT helps Dr. Eptor contribute to the public health goal of reducing the transmission of STIs.

Additional decision: cost. If Dr. Eptor decides to prescribe EPT for Nick's partners, there remains the question about who should handle the cost of the medications. Given that these antibiotics are generally not expensive, Nick may choose to pay for his partners' medications out of pocket. Given the overall public health benefit and economic savings, one might argue that insurers ought to cover both Nick's and his partners' medications, but insurance policies vary in their coverage of EPT. Some state programs, such as California's Medi-Cal program, explicitly prohibit payment of a patient's partners' medications through EPT [8]. Here, we note there is further work to be done in advocating for policies that make EPT more accessible and thus increase its public health impact.

## Social Justice Issues Surrounding EPT

It is important to note that Dr. Eptor might, because of gender norms regarding sexual activity, feel more comfortable prescribing EPT to Nick than if he had a female adolescent patient. Men who have multiple female partners can be lauded for upholding hegemonic masculinity by proving their sexual prowess. Dr. Eptor, while generally uncomfortable, does not seem to have a specific discomfort with the fact that Nick is <u>16</u> <u>years old</u> and has had (at least) three sexual partners. While this could be because of an open mind about sexual activity, it also could be influenced by Nick's gender and the fact that Nick's behavior adheres to general social expectations about teenage boys (i.e., that they have "raging" hormones and want to have sex with as many women as possible). In contrast, had Dr. Eptor been treating a female patient, he might have consciously or unconsciously judged his patient in a way that undermined her credibility and perhaps treated her differently for violating the gender norm of feminine chastity.

Furthermore, it is problematic from clinical and public health ethics—in addition to social and cultural—points of view that the CDC recommends EPT for only heterosexual partners [13]. This limits who may benefit from EPT: if one or more of Nick's recent sexual partners had been male, Dr. Eptor would not be able to prescribe EPT. Homosexual sexual activity is generally considered a contraindication for EPT due to the lack of research on EPT in the LGBT community and because men who have sex with men are at an increased risk for HIV and therefore should be seen by a physician if they are concerned about having contracted any type of STI [13]. One could argue from both clinical and public health ethics perspectives that EPT should be extended to LGBT populations as a matter of justice, as well as to promote the public health goal of reducing STI rates.

#### **Counseling Nick**

In this case, Nick is uncomfortable discussing his own sexual health, and he's rather naive about relevant facts: out of embarrassment, Nick intentionally drove hours to seek care from a nonlocal physician. Nick's sexual activity (and presumably, his nonuse or incorrect use of condoms) has directly caused his current infection as well as the possible infection of his partners. These are certainly reasons for Dr. Eptor to initiate compassionate but frank discussion with Nick about his sexual practices. Beyond providing proper medications, Dr. Eptor is ethically obligated to be a source of trustworthy, clear, and thoughtful counseling to Nick about his sexual health, for the short and the long term.

Many physicians report feeling discomfort in discussing sex with patients [18, 19]; this discomfort may be greater for physicians discussing sexual health with LGBT patients [20]. Dr. Eptor's careful self-reflection is ethically relevant and required of him (and of physicians in similar circumstances) to provide thoughtful, patient-centered care. In his self-reflection, Dr. Eptor might consider: Why is he feeling uncertain about discussing

sexual health and sexuality with a teenager? Is his hesitation and worry about another misdiagnosis influencing his practice in Nick's case? If so, how? Although some physicians feel uncomfortable talking about sex with patients, given that sex and sexuality come into play commonly for adolescent patients, it is imperative that physicians develop self-awareness about their discomfort and that they overcome obstacles that interfere with their capacity to discuss sex and its clinical and public health risks with their patients.

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## **Commentary 2**

# by Hilary E. Fairbrother, MD, MPH

In this case, Dr. Eptor is faced with the decision of how best to treat a probable sexually transmitted infection (STI) in his adolescent patient, Nick, and whether to prescribe for Nick's asymptomatic partners. This case thus pertains to expedited partner therapy (EPT) and partner-delivered patient therapy (PDPT). EPT involves a clinician treating an STI patient's sex partners without actually seeing them in person [1]; PDPT happens when a clinician writes additional prescriptions for the patient's sex partners that are delivered to those partners by the patient. In other words, EPT and PDPT constitute a kind of proxy health care delivery that work best when the clinician's actual in-person patient serves as a reliable messenger. Currently, the Centers for Disease Control and Prevention (CDC) advises that EPT only be used to treat suspected chlamydia and gonorrhea in patients with opposite-sex partners [2]. Multiple ethical and legal questions arise about EPT and PDPT, which are discussed here.

#### EPT and "Nontraditional" Clinician-Patient Relationships

Several considerations favor the use of EPT. One source of ethical complexity in this case, from the clinician's point of view, is the high probability that Nick has infected his sex partners. When one patient is treated and his sex partners are not, infection recurrence for the initially treated patient is possible. In response to this risk for this particular patient, Dr. Eptor could recommend to Nick that he abstain from all sexual relations with any partners until they are all treated and, if need be, cured. There is also a public health risk that the clinician must consider—that others in the community might be infected.

Another ethically relevant consideration has to do with whether the particular STI in question needs to be reported to a state or federal health official. (Clinicians are required, for example, to report confirmed cases of the following to the CDC: chlamydia, gonorrhea, chancroid, hepatitis B, hepatitis C, human immunodeficiency virus (HIV), and primary and secondary syphilis.) In this case, Nick's sex partners are identifiable third parties, so Nick could encourage them to see Dr. Eptor in person for examination, testing, and possible treatment. However, since this kind of "traditional" method of outreach only leads to about 20 percent of sex partners being treated [3], the physician should consider EPT as an ethical means of treating those his patient has put at risk.

Years ago, physicians began employing PDPT in an effort to reach more people potentially infected with STIs and thereby improve both individual patients' health and the health of the public [4]. Since the CDC's release of a white paper on the review and guidance for the use of EPT in 2006 [1], more research has been done. EPT has been shown to be efficacious for chlamydia and gonorrhea in heterosexual sex partners through multiple randomized clinical trials [5] and might also be safe to use in cases of *Trichomonas vaginalis* [6]. Repeat trials have shown EPT to increase the number of sex

partners treated and to lower recurrence and persistence of infections [7-10]. Because of this strong clinical evidence, EPT can be said to benefit both patients and the public. EPT requires that both the original patient's partners and clinicians be willing to interact with each other through an intermediary; this lack of intimacy and connection changes the physician-patient relationship.

EPT is widely practiced by physicians and endorsed by professional societies, with specific statements of support available from the American College of Obstetrics and Gynecology, the American Academy of Pediatrics, the Society for Adolescent Medicine, and the American Medical Association [11-14]. These endorsements suggest that the use of EPT and PDPT can be particularly helpful when patients' sex partners are unlikely or unable to seek evaluation, testing, and treatment.

#### **Principlism and EPT**

Nonmaleficence, beneficence, respect for patient autonomy, and justice [15] are values that can be used to consider Nick's case more from an ethics perspective.

Nonmaleficence is the "do no harm" principle of ethics, and beneficence means doing what is best for a patient. Although it is clear from the above discussion that EPT offers benefit to the patient, is there potential harm to the patients' partners? Some physicians might be concerned that a partner could be given a medication to which he or she has an allergy [16], causing discomfort or even a potentially deadly reaction. While an important consideration, it should be noted that an adverse outcome has never been reported in the seven randomized clinical trials performed on thousands of EPT patients [7]. Another possible objection relates to the limited scope of EPT. Although sex partners might be treated for chlamydia and gonorrhea, they would not be treated or tested for other STIs such as HIV, syphilis, or *Trichomonas vaginalis*. Yet it is known that patients with one STI are at increased risk for co-infection with other STIs [17]. Recent research performed since the publication of the CDC's white paper in 2006 has shown that it may be appropriate for trichomonas vaginalis to be included with chlamydia and gonorrhea as diseases that can be treated via EPT [6, 7]. Also, female patients infected with STIs are at risk for pelvic inflammatory disease (PID), infection extending beyond the cervix; of note, EPT is only prescribed to treat cervicitis. No research studies have been performed to determine the safety of EPT for PID. Due to the length of treatment required and the risks of infertility and systemic infection, a physician must still evaluate female patients with signs and symptoms of PID prior to initiating treatment.

EPT can also lead to a missed opportunity for patient care, and it could delay the identification and assessment of symptoms that might indicate diagnoses other than those for which the partner is being treated. Despite these concerns, the risk to patients who received EPT seems to be low [7]. Partners can be treated via EPT and then encouraged—presumably by the patient who is acting in the role of messenger—to

extend, for lack of a better term, a physician's invitation to be evaluated and assessed more fully. Physicians also cite concerns about the legality of EPT, specifically of prescribing a medication for a person they have never met or examined [18]. Currently, EPT is legal (explicitly allowed) or permissible (not explicitly illegal) in all but four states [19-23].

Respect for autonomy is a third principle to be considered, one expressing the importance of respect for a patient's right to self-determination. This right is protected by two additional concepts of ethical importance: informed consent and confidentiality. Given the remote nature of health care delivery in EPT, is meaningful informed consent possible? While educational materials are available, such as those offered online by New York City's PartnerCare [24] for a patient's sex partners, the remote nature of health care delivery provided via EPT means that clinicians' capacity to respond to patients' questions and concerns is limited. Despite this limitation, as I've argued, the benefits of EPT seem to outweigh the risk that patients might not be fully informed about taking their prescribed medications.

For EPT to work, physicians must convince patients to disclose protected health information, including a diagnosis, to their partners. This is one way physicians can express respect for the autonomy of patients they don't see directly. The Belmont Report states that patients, "to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them" [14]. Informed consent is abrogated by EPT, in that physicians never directly see or interact with the sex partners for whom they are writing prescriptions. It is impossible for full informed consent to be obtained without any sort of direct physician-patient interface. which is partially addressed by including prepared educational materials with the prescription for the sex partners of patients who will be receiving EPT [24]. The benefits of EPT seem to outweigh this very real negative ethical downfall of EPT.

Patient privacy is also violated in EPT, as it is typically necessary for patients to tell their sex partners about their diagnosis. Patient privacy is violated during most direct patient referral interactions as well, so this is not a particular weakness of EPT, but rather a factor of treating the partners of patients infected with sexually transmitted diseases.

Finally, we consider the principle of justice. Our current health care system, despite advances made in coverage by the Affordable Care Act, leaves many patients without access to care. As physicians operating in an imperfect system, it is important to remember that some patients will not be able to seek care due to financial constraints or lack of clinician availability. This might be particularly true for Dr. Eptor's patients, as he practices in a rural area. EPT promotes access and therefore increases justice. EPT, and other forms of remote health care delivery (e.g., telemedicine), despite their drawbacks, increase the chances that persons not willing or able to visit a physician in person—due,

perhaps, to a lack of insurance coverage, social or cultural factors, or immigration status, for example—can be treated.

When considered from a principlist perspective, EPT, despite the reservations noted above, is an ethical way to practice medicine. From a safety standpoint, research shows that EPT is safe for the limited STIs for which it is used. From a practical standpoint, treating patients remotely with an intramuscular injection of ceftriaxone is impossible, but a single 400-milligram dose of oral cefixime cures 96 percent of gonorrhea cases [25]. As long as the limitations of remote practice of health care are identified, considered, and responded to as fully as possible by clinicians practicing EPT, that can be called ethical medicine.

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