

Virtual Mentor

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CINICAL CASE

Ethics of Expedited Partner Therapy

Commentary by Matthew R. Golden, MD, MPH, and Matthew Hogben, PhD, and by Mark A. Levine, MD

Mr. Seabrook, a telephone company employee, decided to visit the health clinic near his workplace because he had a burning sensation when urinating and occasional discharge. Dr. Ellis was staffing the clinic and welcomed him into his office. Mr. Seabrook was a young man in his 20s, and Dr. Ellis recognized his patient's symptoms as probable signs of a sexually transmitted disease. When Dr. Ellis took a sexual history, Mr. Seabrook answered that he had a girlfriend of 3 months who lived in the same town. Dr. Ellis then tested Mr. Seabrook for gonorrhea and chlamydia.

"I'll prescribe some antibiotics to treat the infection, which I think is very likely to be a sexually transmitted disease," said Dr. Ellis. "There are two different pills—one you take just once, and the other you continue taking twice a day for 7 days. Once the test comes back and we know for sure what the infection is, we can discontinue one of those pills." Mr. Seabrook nodded his head, took the prescription, and stood to walk out of the doctor's office.

But Dr. Ellis asked Mr. Seabrook to stay because he wanted to discuss another important matter. Dr. Ellis explained that it was critical that Mr. Seabrook's girlfriend also get medical care because it was very likely that she had been infected with chlamydia, and if she didn't get treatment, she would pass the infection right back to Mr. Seabrook once he finished his course of antibiotics. Furthermore, Dr. Ellis explained that the infection could cause more serious problems for Mr. Seabrook's girlfriend, such as infertility, ectopic pregnancy, and chronic pelvic pain.

"Can we schedule an appointment for her to come in and see me Monday? It will be a brief exam, the same test I did for you, and I could give her a similar prescription if she turns out to have the infection too."

"Actually," said Mr. Seabrook, "I don't think she'll come in to see you. She works two jobs and we live about 45 miles from here. I only came here because it's near my job. Oh, and she doesn't have health insurance."

Dr. Ellis knew the importance of treating Mr. Seabrook's girlfriend and thought of giving Mr. Seabrook a "partner packet"—a course of antibiotics that Mr. Seabrook could give his girlfriend. He feared, however, that Mr. Seabrook might miscommunicate the necessary medical information in delivering the drugs to his

girlfriend. Maybe Mr. Seabrook would be too embarrassed to talk about STDs and never give her the drugs. Moreover, Dr. Ellis felt ambivalent about prescribing for someone he had never met or examined before, and whose medical history and drug allergies he did not know.

Commentary 1

by Matthew R. Golden, MD, MPH, and Matthew Hogben, PhD

This case is fairly typical of what a physician encounters in caring for a man with chlamydial urethritis. A central aspect of that care is ensuring the treatment of the patient's potentially exposed sex partners. Clinicians often do this without actually seeing a patient's partners through expedited partner therapy (EPT). Most commonly, EPT involves giving patients medication or a prescription for their sex partners, a practice called patient-delivered partner therapy (PDPT). PDPT has recently received a lot of attention, including an AMA report related to the ethics of PDPT [1]. In this article, we outline what we consider to be the major ethical issues related to EPT, drawing particular attention to areas in which we believe the AMA report was not balanced or in error.

What Do We Know?

Ethical decisions don't exist in isolation from medical knowledge. As a result, consideration of the ethics of EPT should start with a summary of what we generally know about partner notification and about EPT in particular. Throughout this discussion, we will focus only on gonorrhea and chlamydial infection, the sexually transmitted diseases (STD) for which evidence related to EPT is most thoroughly developed.

At present, U.S. health departments provide partner notification services to fewer than 20 percent of people diagnosed with gonorrhea or chlamydial infection [2]. Randomized trials have shown that these services—in which health department staff interview patients with STDs and try to assure that their partners are notified—can increase the number of partners of male STD clinic patients who receive treatment [3, 4]. No data exist, however, to support the efficacy of this intervention in other populations, and a trial conducted in the United Kingdom found that traditional public health partner services were ineffective when provided outside of the STD clinic setting [5]. Thus, the efficacy of providing traditional public health partner services to the broad population affected by gonorrhea and chlamydial infection remains uncertain. Moreover, health departments have no resources to help clinicians ensure that their patients' partners are treated, so they leave that responsibility to diagnosing clinicians.

Clinicians seldom know what happens to their patients' partners, however. We found that only 17 percent of clinicians interviewed about a patient they had recently treated for chlamydia in King County, Washington, knew whether or not their patient's partner(s) had been treated [6]. In other words, health departments leave the responsibility for partner notification to diagnosing clinicians, and clinicians

typically give that responsibility to the patients themselves. How do the patients do? It's difficult to estimate precisely the percentage of partners that receive treatment, but across a wide spectrum of studies conducted over the last 30 years it seems that approximately one-half of potentially exposed partners receive treatment [7]. Clearly, we have room for improvement.

As part of a public health research group confronting the issue of how to improve STD partner notification a decade ago, we decided we needed a new system. We wanted to develop an approach that was sustainable, evidence based and could be brought to scale to affect public health. We decided to study EPT. In a population-based study of U.S. physicians, we found that approximately one-half already used EPT at least occasionally [8]. Three subsequent randomized controlled trials evaluated EPT for gonorrhea or chlamydial infection [9-11]. All three of these trials found that EPT increased the proportion of partners treated, and all three observed either a significant reduction in reinfection rates in patients whose partners received EPT or a trend toward such a reduction. Thus, EPT was found to improve patient treatment outcome (i.e., reduced risk of reinfection) and to potentially improve the care of partners. These data were consistent with data from observational studies [12, 13] and led to the development of CDC guidelines on EPT as well as guidelines in Tennessee, California, and Washington [14-16].

Ethical Considerations

In deciding whether to provide a patient with PDPT, clinicians confront a number of important ethical considerations that require balancing their obligations to the patient, patient's partner(s), and larger society. In general, four values are paramount in medical ethics: beneficence, nonmaleficence, respect for autonomy, and justice [17].

What is in the best interest of the patient? Insofar as we have good studies showing that PDPT decreases patient reinfection rates in heterosexuals, evidence supports the conclusion that offering PDPT to patients diagnosed with gonorrhea or chlamydia is a superior standard of care. It is worth noting that in the EPT clinical trials, PDPT was offered to all patients who were randomly assigned to study arms that included EPT. Clinicians did not selectively offer PDPT based on their assessment of whether a patient was, in their judgment, more or less likely to see that his or her partner would be treated in the absence of PDPT. (To our knowledge, no study has assessed whether clinicians can accurately predict the likelihood that a patient will assure a partner's treatment.) In one trial, all patients were offered public health assistance in notifying partners, and EPT plus the offer of assistance was more effective than just offering patients assistance in notifying partners. Thus, evidence supports offering PDPT to heterosexual patients with gonorrhea and chlamydia as a routine.

The AMA report on EPT suggests that asking patients to give their partners medication involves a breach of confidentiality since PDPT requires patients to tell their partners about their STD diagnosis [1]. It is true that partner notification involves a loss of patient privacy—diagnosed patients have to notify their partners

before their partners can seek care. However, PDPT does not affect that reality; the loss of privacy is not changed if a patient is offered medication to give a sex partner. Thus, we believe that the issue of confidentiality is irrelevant to the consideration of EPT. Moreover, we do not think anyone would argue that, except in very specific situations (e.g., sexual or physical abuse), it is ethical for patients to not inform sex partners that they may have an STD. Thus offering patients PDPT strikes us as the most ethical course of action for providing patients with gonorrhea or chlamydial infection the best care available.

What is best for the partner? Here the ethical issues are more complicated. PDPT is not optimal medical care for the partner. That said, we believe that partners' interests are best protected by routinely offering patients PDPT, as long as the therapy includes accurate written instructions and information. Some partners may have medical conditions that would be diagnosed if they underwent a complete evaluation and missed if they simply took medication provided by a partner. There is also some risk for allergic reactions. These are clear potential downsides to PDPT. Fortunately, we have some data on these issues.

In a study of more than 8,000 patients in four U.S. STD clinics, we found that 3.8 percent of women evaluated because of sexual contact with a partner who had gonorrhea, chlamydia or nongonococcal urethritis were treated for pelvic inflammatory disease (PID) [18]; these women would not have received standard treatment for PID as part of PDPT. However, some would presumably have sought care because of symptoms, others would have been adequately treated with the medications provided as PDPT [19], and, given the nonspecificity of the clinical diagnosis of PID, some almost certainly did not have an upper genital tract infection. Thus, the number of cases of PID that go untreated as a result of PDPT is most likely very small, and, depending on how much PDPT increases partner treatment, PDPT may actually increase the treatment of PID. With the exception of infection with *Trichomonas vaginalis*—a pathogen for which most providers do not routinely test—other diagnoses appear to be very rare in heterosexuals evaluated because of a partner's STD diagnosis [18].

We have fewer data on the risk of adverse drug reactions resulting from PDPT. PDPT could increase the risk of adverse drug reactions if partners who knew they had a history of an allergic reaction to macrolides, penicillins, or cephalosporins took one of those medications in spite of a written warning not to do so. To date, however, there is no evidence that this is a significant problem. We have provided PDPT to thousands of patients in King County since 1998. The health department distributes PDPT with information and a telephone number to contact about adverse events, and a case of anaphylaxis has yet to be reported. Similarly, the California State Department of Health maintained a hotline for reports of major adverse reactions from EPT for several years and never received a report. Thus, what evidence we have suggests that more partners are treated when patients with gonorrhea or chlamydia receive PDPT; very few have concurrent infections that would routinely

be treated if they sought medical evaluations; and avertable, major adverse drug reactions are very rare.

The ethical dilemma revolves around whether partners can make informed decisions about these risks and their medical care. Here we believe that the principle of respect for autonomy should take precedence. When PDPT includes appropriate written information, we believe that partners can make an informed decision about whether or not they wish to take the provided medication or follow the accompanying advice to seek a complete medical evaluation. (Illiterate patients, very young persons, and other groups may not be good candidates for routine PDPT because of this concern.) As with the issue of confidentiality discussed above, concerns about partner informed consent are not limited to partners receiving PDPT; they also affect partners who do not receive PDPT. When patients are told to notify partners of their STD diagnosis—particularly when they are asked to do so with no written information—we don't really know what they tell their sex partners. Insofar as PDPT promotes more widespread provision of written information for partners, it may improve informed consent. To the extent that PDPT increases notification rates (equivalent or improved rates were seen across all trials evaluating EPT), a larger proportion of partners will be exposed to instructions to seek evaluation and take other appropriate actions (e.g., abstain from sex for 7 days).

The principle of justice also argues for the need for PDPT. Unfortunately, our medical care system is not just, and many people have limited access to care. For some partners, PDPT may be the only way to receive treatment. As medical professionals, we should actively advocate for a more equitable medical care system, one in which everyone who wants to see a medical professional can do so. But until such a system is in place, some access to care is probably better than none at all. Again, we are aware of no evidence to suggest that medical professionals can accurately gauge whether a patient's sex partners have insurance or good access to medical care. Given that reality, the ethical course of action is to offer PDPT routinely to patients with gonorrhea and chlamydial infection.

What is best for the society? Remarkably, it is here that the data are weakest. While we have some data that a public health program promoting EPT use can increase the proportion of partners treated in the population [20], we do not have data that it actually affects the prevalence or incidence of STD. Of course, we don't have that type of data to support any approach to partner notification or intervention currently in place to control STDs. It makes intuitive sense that treating more partners should prevent ongoing STD transmission, and that hypothesis is supported by mathematical modeling studies [21, 22]. Thus, while we certainly need better data on this critical issue, what evidence we have supports that idea that EPT could improve the public health.

Conclusions

Physicians treating patients for gonorrhea or chlamydia are ethically obliged to make a good faith effort to assure that their patients' sex partners also receive treatment.

Health departments around the United States are increasingly advocating the use of EPT as a tool to help clinicians achieve that goal. EPT is not legal in all states, and clinicians should assess the legal status of EPT in their state before providing it. The CDC maintains an Internet site that provides information on the legality of EPT [23]. While there are genuine ethical dilemmas involved in EPT, we believe that, as long as medications are provided with appropriate written information, the preponderance of ethical consideration favors routinely offering EPT to heterosexuals with gonorrhea or chlamydial infection.

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Commentary 2

by Mark A. Levine, MD

This case outlines a number of issues that have long concerned thoughtful practitioners: issues of trust, effectiveness, safety, confidentiality, liability, and public health. While there has been a recent flurry of policies and publications in this area, the concerns are not new, though perhaps newly nuanced [1-3].

Physicians have a proud tradition of commitment to provide ideal care. They also have obligations to do no harm and help patients whenever they can. As is obvious from this case, it is not always possible to honor those commitments at the same time. Failure to treat both this patient and his partner will continue to expose the patient to chlamydia if their relationship continues, and, even if it does not, his partner is a reservoir of disease that presents a threat to public health. Ideal care would be the simultaneous medical evaluation and treatment of the patient and all of his sexual contacts. The patient in this case has told Dr. Ellis that his partner will not seek medical evaluation. Thus, the practitioner is faced with a choice of less-than-ideal strategies. Which professional imperatives should be honored and which should be ignored?

The provision of therapy for sex partners of patients with certain sexually transmitted diseases, primarily chlamydia, without an intervening medical evaluation or professional prevention counseling is known as expedited partner therapy—named because the treatment is delivered at the discretion of the patient [1, 2].

For years, practitioners surreptitiously provided double doses of therapy to patients with STDs, intending that one-half would be taken by the patient's partner. This was generally done in circumstances where the partner would be unlikely to seek medical attention. The strategy was assumed to be the best practical way of preventing disease recurrence from exposure to a known source of infection. Frequently it was undertaken in violation of state licensing laws that explicitly required an established patient-physician relationship as a condition of treatment. It was also usually performed in the absence of prepared educational material and with great variety in the content and quality of patient instruction. Even today, less than one-quarter of state medical practice laws explicitly approve expedited partner therapy [3].

In the last few years, the Centers for Disease Control and Prevention [1] and the American Medical Association [2, 4] have collaborated on a series of recommendations that clearly outline the circumstances and requirements for the appropriate use of expedited partner therapy. These recommendations are: (1) use only in certain circumstances—currently gonorrheal and chlamydial infections in heterosexual women and men—when other management strategies are impractical or unsuccessful; (2) do not use for the treatment of syphilis or trichomoniasis or for men who have sex with men; (3) encourage the intended recipient of expedited partner therapy to seek medical attention in addition to accepting therapy; (4) educate the recipient through written materials that accompany medication, by counseling of the index case, and, when practical, through personal counseling by a pharmacist or other professional; and (5) be aware of state practice laws and regulations and public health requirements that limit the use of expedited partner therapy.

In addition to providing quality care for their individual patients, physicians have a health policy role. Principle III of the AMA's *Code of Medical Ethics* states, "A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient" [5]. With the increasing recognition of medical and public health benefits of expedited partner therapy, physicians are encouraged to work with their state legislatures and public health agencies to remove legal and regulatory impediments to its use.

How do these policies pertain to the care of Mr. Seabrook in the above case? Certainly Dr. Ellis was correct to inquire about Mr. Seabrook's sexual partner. Yet, he should not assume that Mr. Seabrook has a single, heterosexual partner. A more open-ended inquiry, such as, "Can you tell me about your sexual activity," could have opened a door to possible acknowledgement of more than one partner or same-sex experiences that would have influenced management significantly. For instance, expedited partner therapy is not recommended for partners of men who have sex with men even if they also have heterosexual partners.

How should Dr. Ellis consider the observation that Mr. Seabrook's girlfriend lacks health insurance? This should not change the clinical recommendation that she receive medical evaluation and treatment, although it may influence her decision of where to seek care.

Dr. Ellis is fortunate to have a "partner pack" available. This implies that some forethought has been given to expedited partner therapy on the health clinic's behalf. The educational packet for the patient and his partner regarding infection with gonorrhea and chlamydia should include information to facilitate the sensitive discussion between a naive patient and his or her partner that encourages the partner to seek medical care.

If Dr. Ellis concludes that expedited partner therapy is the best course of action in this situation, he must give some thought to how the therapy will be delivered. He

could write a prescription in the name of the person that Mr. Seabrook identifies as his partner. If Mr. Seabrook is uncomfortable providing such identifying information, Dr. Ellis might be tempted to double the dosage of the medication he prescribes for Mr. Seabrook, but this could be a violation of state regulation and perhaps even insurance fraud. A third option is to write a prescription for the indicated medication(s) while leaving the name of the patient blank. Unfortunately, this, too, may be a violation of state regulation.

The ideal decisions for Dr. Ellis to make are: (1) obtain as complete a sexual history from Mr. Seabrook as possible; (2) review the partner pack to assure that it contains thorough and sensitive clinical information intended to persuade the partner to seek medical care for the exposure and evaluation of possible concomitant health problems; (3) write a prescription for an unnamed patient for the indicated medications in the event that the partner elects not to seek medical attention; (4) report Mr. Seabrook's infection in compliance with pertinent regulatory requirements; and (5) advocate for changes in a state law or regulations, if necessary, to remove impediments to expedited partner therapy.

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