REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 6-A-08

Subject: Expedited Partner Therapy

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Referred to: Reference Committee on Amendments to Constitution and Bylaws

(Raymond G. Christensen, MD, Chair)

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INTRODUCTION

The Centers for Disease Control and Prevention (CDC) define expedited partner therapy (EPT) as "the practice of treating sex partners of patients with sexually transmitted diseases (STD) without an intervening medical evaluation or professional prevention counseling." EPT is typically implemented via patient-delivered partner therapy (PDPT). Under this model, health care professionals offer patients antimicrobial agents to give to their partners outside of a clinical setting. This report focuses specifically on the ethical issues associated with the use of expedited partner therapy per CDC guidelines.

EXPEDITED PARTNER THERAPY AND PUBLIC HEALTH

Public health efforts to control STDs have traditionally relied on partner notification.² According to the World Health Organization, partner notification includes "identifying sex partners, informing them of their exposure, ensuring evaluation or treatment, and providing advice on preventing further infections." This process of contact between physician and partner, known as provider referral, increases the likelihood that partners who have been exposed to STDs will seek appropriate medical treatment. However, it has been estimated that as few as 4% of health care professionals actively conducted partner notification on behalf of patients with STDs. Thus, while provider referral is effective, it is often underutilized in practice.

Public health efforts to reach the partners of patients with STDs have been frustrated by several problems. The resources to provide assistance are frequently inadequate, especially in areas with the highest prevalence of disease. ^{7,8} One study found that fewer than 20% of people diagnosed with chlamydia or gonorrhea received assistance from health departments in notifying their partners. ² Adding to these constraints is the observation that despite a legal requirement, many cases of sexually transmitted disease are never reported to public health authorities. ⁹ Thus many patients are left on their own to notify sexual partners. Lacking appropriate knowledge and support,

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patients may not notify their partners or may communicate information ineffectively.

Consequently, partner treatment frequently does not occur. One strategy to increase the rate of treatment for the partners of patients with STDs is the practice of expedited partner therapy. The appropriate use of EPT has resulted in more partner treatment than standard referral of patients among patients infected with gonorrhea or chlamydia. It may also be less costly than the standard practice of patient or provider referral in the treatment of certain STDs.

As expedited partner therapy began to receive consideration within the medical community, the American Medical Association (AMA) worked with the CDC to review the scientific literature surrounding EPT and studied issues associated with the practice. The AMA Council on Science and Public Health made recommendations based on this collaboration that called for the AMA to work with the CDC on a report and encouraged continued research into the risks and harms associated with EPT. When the CDC's report was released in 2006, it formally endorsed the use of patient-directed partner therapy as an efficient means to treat sexual partners of heterosexual men[†] and women infected with chlamydia or gonorrhea. The report further stated that EPT represented only one of many strategies available to physicians. It was recommended that EPT not be utilized in place of standard patient referral or provider-assisted referral, and that partners be provided with information instructing them to seek traditional health care in addition to the patient-delivered therapy. On reviewing the CDC report and on recommendation of the Council on Science and Public Health, the AMA House of Delegates voted to formally support the CDC guidelines.

ETHICAL CONSIDERATIONS IN THE PROVISION OF EPT SERVICES

Expedited partner therapy can help to fulfill physicians' ethical obligations to promote public health (see Principle VII of the AMA's *Principles of Medical Ethics*). However, ethical concerns arise whenever treatment occurs outside of a traditional patient-physician relationship.

The reliance on EPT programs for treatment is problematic because they require physicians to prescribe medications to individuals whom they have not themselves examined (see E-8.06, "Prescribing and Dispensing Drugs and Devices"). Thus, the patients' partners are not afforded the opportunity to discuss questions or concerns with the prescribing physician, to present relevant aspects of their medical history, or to establish treatment goals (see E-10.02, "Patient Responsibilities"). EPT programs also abrogate the standard informed consent process by relying on the patient, usually a layperson, rather than a physician to inform partners of the risks, benefits, and available alternatives associated with treatment. If this information is not presented correctly, an informed medical decision is not possible (see E-8.08, "Informed Consent"). Further, confidentiality is compromised as the patient is being called upon to communicate his or her personal medical issues with his or her sexual partners (see E-5.05, "Confidentiality").

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[†] The CDC report excluded the use of EPT for homosexual men based on various other risk factors that make it more appropriate to require a patient-physician relationship prior to providing treatment for sexually transmitted diseases.

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An additional concern is that EPT is performed independent of the partner's usual care situation and is thus potentially disruptive of care continuity (see E-10.015, "The Patient-Physician Relationship"). Moreover, the provision of EPT outside a patient-physician relationship can increase the potential for allergic reactions or other preventable adverse events.¹²

Because of these potential harms, physicians must emphasize to patients that EPT is not intended to replace standard physician-delivered treatment for their sexual partners. Instead, EPT is more appropriately regarded as a secondary treatment option that is a less desirable alternative. With this understanding, physicians should first recommend to patients that their partners seek medical care within a traditional setting. If despite this recommendation, the physician reasonably believes that the patient's partners will be unable or unwilling to seek traditional medical care, it is then ethical for the physician to provide EPT as a less desirable option.

When participating in EPT, physicians must educate patients about the EPT process and answer any questions that they might have. The physician must also provide patients with educational materials to share with their partners that explain EPT, provide rationale and instructions regarding the use of supplied medications, illuminate the potential risks posed by additional STDs that may be left untreated by the medication, and emphasize the importance of seeking a formal clinical evaluation. Finally, physicians should make all reasonable efforts to assist patients in referring their partners to appropriate health care professionals.

LEGAL ISSUES IN THE PROVISION OF EXPEDITED PARTNER THERAPY

The use of EPT requires patients' partners to receive care from individuals (the index patients) who are not appropriately trained and duly licensed to dispense medications (see E-3.03, "Allied Health Professionals"). This practice may potentially conflict with state laws that prohibit a physician from aiding an unlicensed person in the practice of medicine (see E-3.01, "Non-Scientific Practitioners") and prohibit pharmacists from dispensing medication for an individual when there is no patient-physician relationship or the individual is not named on the prescription label.

In roughly 75% of jurisdictions (fifty states, the District of Columbia, and Puerto Rico), EPT is either expressly permitted or potentially allowed. Twelve states recognize EPT as a valid mechanism of treatment. Thirteen states effectively prohibit EPT, primarily through requirements for patient examination or patient-physician relationships. The remaining jurisdictions do not explicitly authorize EPT, but laws, regulations, rulings, or other legal authorities create an ambiguity as to its permissibility—there is no specific guidance to support or prohibit the use of EPT. 14

 Recent trends indicate a growing acceptance of EPT as a legally valid treatment option. For example, in Texas, although state laws and regulations do not favor the use of EPT,¹⁴ the Texas Department of State Health Services explicitly views EPT as "an important and useful option for facilitating partner treatment of sexually transmitted diseases."¹⁵ This may create momentum in that state to clearly legalize its use. Additionally, state legislatures, including those in Arizona and Illinois, have introduced legislation to legalize EPT.

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Although some physicians may hesitate to use EPT out of concern about legal risks, it is important to remember that the legal status of EPT is constantly changing and EPT appears to be gaining more widespread legal acceptance. Physicians are therefore advised to become familiar with their state's laws concerning EPT; they may also want to seek counsel prior to its use.

CONCLUSION

Expedited partner therapy has been demonstrated to be a clinically effective strategy for the treatment and limitation of spread of a limited number of sexually transmitted infections. As such, physicians should recognize the practice as a valid tool for promoting public health when appropriately indicated. However, EPT in the absence of a traditional patient-physician relationship creates distinct ethical concerns pertaining to informed consent, confidentiality, and patient safety. Physicians should therefore emphasize to patients that medical care within a patient-physician relationship is preferred. Only in circumstances when this is impossible or unlikely should EPT be considered. While it may be ethical to use EPT to minimize the negative health consequences of sexually-transmitted diseases, physicians should make reasonable efforts to refer the partners of their patients to appropriate health care professionals.

RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder of the report be filed:

Expedited Partner Therapy (EPT) is the practice of treating the sex partners of patients with sexually transmitted diseases via patient-delivered partner therapy without the partner receiving a medical evaluation or professional prevention counseling. While this practice is presently recommended by the Centers for Disease Control and Prevention for use in very limited circumstances (for gonorrhea or chlamydial infection in heterosexual men and women), EPT may be recommended for additional applications in the future.

Although EPT has been demonstrated to be effective at reducing the burden of certain diseases, it also has ethical implications. EPT potentially abrogates the standard informed consent process, compromises continuity of care for patients' partners, encroaches upon the privacy of patients and their partners, increases the possibility of harm by a medical or allergic reaction, leaves other diseases or complications undiagnosed, and may violate state practice laws. The following guidelines are offered for use in establishing whether EPT is appropriate:

(1) Physicians should determine the need for EPT by engaging in open discussions with patients to ascertain their partners' abilities to access medical services. Only if the physician reasonably believes that a patient's partner(s) will be unwilling or unable to seek treatment within the context of a traditional patient-physician relationship should the use of EPT be considered.

1 2	(2) Prior to initiating EPT, physicians are advised to seek the guidance of public health officials, as well as determine the legal status of EPT in their state.
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4	(3) If the physician chooses to initiate EPT, he or she must provide patients with appropriate
5	instructions regarding EPT and its accompanying medications and answers to any questions
6	that they may have.
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8	(4) Physicians must provide patients with educational material to share with their partners that
9	encourages the partners to consult a physician as a preferred alternative to EPT, and that
10	discloses the risk of potential adverse drug reactions and the possibility of dangerous
11	interactions between the patient-delivered therapy and other medications that the partner
12	may be taking. The partner should also be informed that he or she may be affected by other
13	STDs that may be left untreated by the delivered medicine.
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15	(5) The treating physician should also make reasonable efforts to refer a patient's partner(s) to
16	appropriate health care professionals.
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18	(New HOD/CEJA Policy)

Fiscal Note: Staff cost estimated at less than \$500 to implement.

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