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A Historical Note on the Association Between the Legal Status of Expedited Partner Therapy and Physician Practice

Ryan Cramer, JD, MPH*, Matthew Hogben, PhD*, H. Hunter Handsfield, MD†

*Division of STD Prevention, Centers for Disease Control and Prevention, Atlanta, GA

†University of Washington Center for AIDS and STD, Seattle, WA

Abstract

Potential legal liability for practicing expedited partner therapy is a common concern among providers, although it has been uncertain how these concerns translate into clinical practice. This study suggests that providers are more likely to practice expedited partner therapy in more favorable legal environments.

Expedited partner therapy (EPT) is the practice of arranging treatment for partners of individuals diagnosed as having a sexually transmitted disease (STD) without an intervening clinical evaluation.^{1,2} In randomized controlled trials, the practice of EPT in the form of patient-delivered partner therapy has resulted in increased rates of partner treatment and reductions in index patient reinfection compared with clinic-based partner treatment.^{3–6} Implementation efforts have shown varied rates of index patient uptake and reinfection; partner treatment has been less commonly measured.⁷ A survey of US physicians on STD-related clinical practices in 1999 to 2000 showed that EPT was widely used to treat partners of women diagnosed as having chlamydial infection or gonorrhea.^{8,9} Using that survey and a state-by-state assessment of EPT-relevant laws,¹⁰ we examined the association between state legal environments and physician practice of EPT.

One of the most prominent policy issues concerning EPT is the potential legal liability of providers. The primary forms of potential liability are civil malpractice liability and professional censure, which arise from providing or facilitating access to prescription antibiotic treatment in the absence of an established provider-patient relationship.¹¹ Concurrently, providers may understand that EPT potentially improves the health outcomes of their patients with chlamydial infection or gonorrhea, creating tension between optimal patient care and medicolegal considerations.

Malpractice is the legal doctrine of negligence as applied to professionals. Essentially, negligence is a failure to act reasonably, which results in injuries to another. Negligence requires 4 elements be proven: a duty to act reasonably (which, for providers, is their standard of care), a breach of this duty, the breach must have caused harm, and the resulting harm must be in a form for which compensation is available (i.e., actual physical or

Correspondence: Ryan Cramer, JD, MPH, CDC Mail Stop E-02 Atlanta, GA 30333. rcramer@cdc.gov.

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monetary loss). If a provider is held liable for malpractice, he or she typically is compelled to compensate the patient plaintiff for the harm. Professional censure is similar to malpractice in that a licensure board can censure a provider, through fines and license suspension or revocation, for providing care that is deemed below the standard of care. An important distinction, however, is that censure requires only that the provider's conduct is below the standard of care regardless of whether harm (e.g., an adverse outcome) occurs. As such, only the duty and breach elements of negligence are implicated, whereas proof of injury is not necessary.¹²

To illustrate this distinction, all drivers are regulated by the "rules of the road": laws that regulate the manner in which one drives, such as speed and using turn signals. Drivers are further "regulated" by the possibility of being sued by others for harmful, careless driving. Take a hypothetical situation in which one attempts to drive blindfolded and is pulled over by a police officer immediately upon leaving his or her driveway. The driver will almost certainly be cited for violating a law forbidding reckless driving because he or she failed to drive in a reasonably safe manner. However, despite driving in a manner that is probably below the standard of care, without hitting another person or another's property, the driver cannot be sued for negligence because he or she did not cause any harm. The police officer's authority to cite the driver for reckless driving is analogous to the licensure board's authority to censure a provider for providing health care services below the standard of care; the lack of anyone's ability to sue the driver for negligence is analogous to a provider's potential for malpractice liability. Accordingly, professional censure is seen as the most realistic legal barrier to the practice of EPT because the risk of harm (an overt adverse reaction) is low for the medications recommended for EPT and without harm, a malpractice suit is not possible.¹ However, where a licensure board finds the practice of EPT to be below the standard of care, a provider could be censured regardless of whether an adverse reaction occurs.

Expedited partner therapy was recommended by the Centers for Disease Control and Prevention (CDC) in 2006.^{1,2} Owing to concerns expressed by health care providers and their professional organizations, the potential for legal liability was expressly considered during the expert consultation that informed CDC's recommendation. Because of these concerns, soon after the 2006 publication of guidance, CDC and the Centers for Law and the Public's Health evaluated the legal status of EPT and published their findings in 2008 (2008 EPT legal analysis).¹⁰ Since then, several states have adopted laws that expressly permit EPT, effectively eliminating the argument that its practice is below the standard of care, whereas other states have taken actions to clarify their existing permissive legal environment. To further facilitate policy making, in 2011 CDC and Arizona State University released the Legal/Policy Toolkit for Adoption and Implementation of Expedited Partner Therapy.¹³ The purpose of the toolkit is to inform state and local policy makers of the legal and policy considerations surrounding EPT and to help them address these considerations consistent with CDC recommendations and tailored to the characteristics of their state.

Although it is known that physicians are aware of the legal issues raised by EPT,¹⁴ little is known as to how these concerns translate to provider practice. Using data from a 1999 to 2000 survey of STD-related physician practices,^{8,9} we analyzed the relationship between the legal status of EPT and the proportion of respondents who reported that they had given

patients diagnosed as having chlamydial infection or gonorrhea medications to give to their partners. The 2008 EPT legal analysis classified each state and the District of Columbia according to whether EPT was permissible (11 states), potentially allowable (27 states), or likely prohibited (13 states).¹⁰

The 1999 to 2000 provider survey was mailed to 7300 US physicians (randomly selected from the AMA Master file) and collected responses to numerous questions concerning STD care. The detailed methods and outcomes of the survey have been published elsewhere.^{8,9} Of 4223 physicians responding to the survey (70% response rate), 2538 (60.1%) reported diagnosing chlamydia and 1873 (44.4%) reported diagnosing gonorrhea in at least 1 patient in the preceding 12 months.⁹ Among physicians who had diagnosed chlamydial or gonococcal infection, the survey asked whether they had ever used EPT for partner management through patient-delivered therapy for chlamydial or gonococcal infections. As shown in Table 1, physicians in states where EPT was legally permissible in 2006 to 2007 were more likely to use EPT in managing patients with gonorrhea (odds ratio [OR], 1.35; 95% confidence interval [CI], 1.12–1.62) and more likely to use EPT in chlamydia management (OR, 1.45; 95% CI, 1.21–1.74), compared with states in which EPT was legally prohibited. Physicians in states where EPT was potentially allowable fell between the other 2 groups, with a nonsignificant trend toward increased use compared with states with prohibitive laws. The linear trend in legal permissiveness was statistically significant for both chlamydial infection ($\chi^2 = 16.19$, $P < 0.001$) and gonorrhea ($\chi^2 = 10.46$, $P = 0.001$).

The historic nature of the data and the lapse of 7 to 8 years between the 1999 and 2000 provider survey and the 2008 EPT legal analysis is the principal limitation of this analysis. However, only California and Tennessee enacted laws authorizing EPT in the intervening period (2001 and 2002, respectively), so the legal landscape in 2008 was virtually indistinguishable from that during the survey (1999–2000). Nonetheless, removing California and Tennessee data from the analysis did not materially change the outcomes for either gonorrhea or chlamydia ($P = 0.001$; data not shown). Furthermore, if EPT usage increased after the enactment of laws in these states, then our findings would underestimate the true effect of permissive legislation. Conversely, it is possible that EPT practice in areas where it was prohibited was under-reported based on the potential reticence to acknowledge the practice. Nevertheless, a survey of medical and pharmacy boards from 2005 suggested that medical opinions on legality and the 2008 EPT legal analysis were only weakly related.¹⁵

In summary, the present analysis shows that the legal environment is positively associated with use of EPT in managing patients with chlamydial infections and gonorrhea. As for most ecologic analyses, causality cannot be inferred from our findings. That the legal environment influences physicians' use of EPT and that a collective interest in EPT affects legal change are both plausible. Both influences may also interact with one another. Therefore, a permissive legal landscape should not be mistaken for programmatic interest in EPT or even agreement that EPT is a good strategy. Similarly, a prohibitive landscape need not imply a lack of interest in EPT. By 2012, almost half the states with initial prohibitions against EPT had either explicitly legalized it or were in the process of doing so.¹⁶ States classified as having permissive environments now number 32 versus 11 states in 2008, with most of them

now expressly authorizing EPT.¹⁶ The next steps in optimizing EPT should focus on increasing eligible patient uptake in areas where the practice is authorized and coping with the potential for gonococcal infections that are resistant to oral medication. Moving forward, research should investigate the current effects of legislation on provider practice and awareness, potentially reexamining the associations found in this note and some longitudinal analyses.

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Ever Provided EPT Among Physicians Who Diagnosed at Least 1 Chlamydial or Gonococcal Infection in the Past 12 mo by State EPT Legal Category

TABLE 1.

STD	Legal Category in 2008	Using EPT, n (%)	OR (95% CI)	P
Gonorrhea	Prohibited	415/949 (44)	Referent	—
	Potentially allowable	735/1632 (45)	1.05 (0.90–1.24)	0.520
Chlamydial infection	Permitted	479/936 (51)	1.35 (1.12–1.62)	0.001
	Prohibited	455/946 (48)	Referent	—
	Potentially allowable	812/1627 (50)	1.08 (0.92–1.26)	0.376
	Permitted	539/939 (57)	1.45 (1.21–1.74)	<0.001