Legal and Policy Issues Concerning Expedited Partner Therapy (EPT)

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Public Health Law Network

- Funded by the Robert Wood Johnson Foundation
- The Network works with public health lawyers, practitioners, and others to improve the public's health through law
- The Western Region connects and serves individuals and organizations through technical assistance, training, and other efforts
- www.publichealthlawnetwork.org
Disclaimer

- Please note that information provided during this session does not constitute legal advice.

- Please seek guidance from your legal counsel for specific, legal advice.
Overview

- Brief assessment of the public health impacts of Chlamydia and Gonorrhea
- Expedited Partner Therapy (EPT)
  - CDC and other organizations’ support and guidance
- Legal barriers/facilitators project
  - **Stage 1**: Legal landscape of EPT
  - **Stage 2**: Identify and assess legal and policy barriers to the practice of EPT and adoption of laws and policies authorizing EPT
Public Health Impacts

Chlamydia (CT)

- 1,244,180 new cases reported to CDC (2009) (actual cases are >)
- Most commonly-reported infectious disease in the U.S.
- Bacterial infection, easily transmitted via sexual contact, asymptomatic
- Women are frequently re-infected if their partners are not treated

Gonorrhea (GC)

- 301,174 new cases reported to CDC (2009) (actual cases are >)
- Second most commonly-reported infectious disease
- Bacterial infection, easily transmitted via sexual contact, asymptomatic
- Persons infected may be more likely to transmit or contract HIV

http://www.cdc.gov/std/chlamydia/STDFact-Chlamydia.htm
http://www.cdc.gov/std/Gonorrhea/STDFact-gonorrhea.htm
Womens’ Health Consequences

Chlamydia & Gonorrhea

Pelvic Inflammatory Disease (10-20%)

Infertility (20%)

Ectopic Pregnancy (9%)

Chronic Pelvic Pain (18%)
Breaking the CT and GC Chain
Expedited Partner Therapy

- EPT is a component of comprehensive partner services for STI treatment recommended by CDC
- Partners are provided treatment through the patient without an intervening clinical assessment of the partner
- Patients typically deliver either medications or prescriptions to their partners
Expedited Partner Therapy - Illustrated
“[E]vidence indicates that EPT should be available to clinicians as an option for partner management. . . that does not replace other strategies, such as standard patient referral or provider-assisted referral . . . .”

1. “When medical evaluation, counseling, and treatment of partners cannot be done because of the particular circumstances of a patient or partner or because of resource limitations, other partner management options can be considered….

2. Patient-delivered therapy (i.e., via medications or prescriptions) can prevent re-infection of index cases and has been associated with a higher likelihood of partner notification, compared with unassisted patient referral of partners.
3. Medications and prescriptions for patient-delivered therapy should be accompanied by treatment instructions, appropriate warnings about taking medications if pregnant, general health counseling, and advice that partners should seek personal medical evaluations, . . . .”

National Support for EPT


- **Society for Adolescent Medicine & American Academy of Pediatrics**
  - Endorses use of EPT as an option for STI care among partners exposed within 60 days to heterosexual males/females with CT or GC when other partner management strategies are impractical/unsuccessful
  - Supports modifying existing laws impeding EPT implementation

- **American Bar Association 2008 Recommendation**
  - Urges jurisdictions to support the removal of legal barriers to the appropriate use of EPT by HCWs
Matthew Golden et al. suggests in 2005 based on their survey study of representatives of state boards of medicine and pharmacy that 88% of participants perceived EPT as either “illegal” or of “uncertain illegality.”

Legal Barriers to EPT

- Specific legal authorization
- Scope of practice limits
- Drug dispensing and labeling issues
- Liability concerns
- Health insurance limitations
Assessing Legal and Policy Issues Concerning EPT for Sexually Transmitted Infections
Stage 1 - Legal Assessment

- Initial assessment of the legal environment underlying the practice of EPT across states
  - Identify major legal issues
  - Clarify relevant laws, ethics, and policies that facilitate or impede EPT
  - Offer legal interpretations, strategies, or proposals for reform to facilitate EPT across jurisdictions consistent with public health laws and policies
Stage 1 - Methodology

- Examine statutes, bills, regulations, cases, opinions, and other laws and policies in all states in 4 key areas:

1. Laws concerning the ability of physicians to provide a prescription to a patient’s partner without prior evaluation of the partner

2. Laws concerning the ability of other health care personnel (nurses, physicians’ assistants, pharmacists) to provide a prescription to a patient’s partner without prior evaluation

3. Laws concerning prescription requirements (e.g., patient-specific information requirements)

4. Laws concerning public health authorization for EPT (via incorporation by reference or other techniques)
Stage 1 - Limitations

- Reviews are systematic and comprehensive, but not exhaustive
- Interpreting non-binding legal sources, such as policy guidance documents or administrative decisions, is complicated
- Comparative snapshot of legal provisions that may highlight laws concerning EPT in a given jurisdiction based on currently available information
- Jurisdiction-specific feedback can clarify specific legal issues
Stage 1 - Products

- Comprehensive table of state and territorial legal authorities to assist law and policy makers, STD prevention professionals, and HCWs assess the legality of EPT available at: http://www.cdc.gov/std/ept/legal/default.htm

EPT Legal Status 2006

- **EPT is Permissible** - 10 states
- **EPT is Likely Prohibited** - 13 states
- **EPT is Potentially Allowable** - 29 states
“Prescribing, dispensing or furnishing a prescription medication or a prescription-only device (as defined in § 32-1901) to a person unless the licensee first conducts a physical examination of that person or has previously established a doctor-patient relationship. This subdivision does not apply to:

(v) Prescriptions written or antimicrobials dispensed to a contact (as defined in § 36-661) who is believed to have had significant exposure risk with another person who has been diagnosed with a communicable disease by the prescribing or dispensing physician.”

Stage 2 - EPT Legal Consultation

Goal: identify legal barriers and develop responsive tools

Consultation on May 13, 2010 at CDC, Atlanta:

1. Barriers to Implementing EPT in Practice: Liability
2. Barriers to Implementing EPT in Practice: Regulatory and Licensure Provisions
3. Legal and Political Barriers to Adoption of Laws and Policies Authorizing EPT
4. Identification and Development of Tools to Address Identified Barriers
I. Barriers to Implementing EPT: Liability

- **General:** Liability concerns vary among states
- **Providers:** lost opportunity to test; risks and adverse reactions; loss of control over distributed drug; partner violence
- **Entities:** sovereign immunity may apply to governmental public health agencies, but not private entities; insurers reluctant to cover partners
- **Patients:** confidentiality concerns and partner violence
II. Barriers to Implementing EPT: Regulatory and Licensure Provisions

- **Financing**
  - Double prescription vs. separate prescription for partners
  - Insurance coverage
  - Federal and state payments via Medicaid programs

- **Minors**
  - Distribution to a minor whose partner is also a minor
  - Involvement of state agencies that oversee child services
  - Health concerns relating to infertility in young women or HIV

- **Medical Licensure**
  - Collaborative practice agreements; administrative rules; scope of practice limitations; medical board interpretations

- **Privacy Concerns**
III. Barriers Impeding EPT Authorization

What has worked:

- Explicit statutory authorization
- Programs initiated at the local level
- Support from organizations/partners
- Advisory committees (Medical Director)
- Rule changes at the administrative level including medical boards
III. Barriers Impeding EPT Authorization

○ What has not worked:

- **Lack of support** from key players (medical boards, insurers)
- **Conflicts** with pharmacy laws
- **Misinformation** on efficacy of EPT
- **Lack of involvement** of outside organizations
- **Redefining** key legal terms (e.g., “dispense”)
- **Local idiosyncrasies**
IV. Tools to Address Legal Barriers

Following the consultation at CDC, we sought guidance from state and local practitioners as to the types of practical, applied tools they needed to facilitate the implementation or authorization of EPT in their jurisdictions.
## Menu of Potential Tools

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CDC EPT Legal Toolkit

1) **Sample State Legislative Language** on Liability Issues Related to EPT

2) **Discussion of Selected Issues Related to Practitioners’ Liability** for Harms to Partners Through EPT

3) **Frequently Asked Questions:** Health Information Privacy for Physicians, Pharmacists, and Other Healthcare Practitioners Concerning EPT

4) **Considerations for Drafting and Implementing Legislation and Regulations** Concerning EPT
Conclusion and Acknowledgements

- Special thanks to Lexi White and Chase Millea for their research and contributions to this presentation

- CDC’s EPT Legal Status

- ASU’s Public Health Law and Policy
  http://www.law.asu.edu/publichealthlaw/PublicHealthLaw/Projects.aspx#EPT

- Questions, comments, thoughts?