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Report 7 of the Council on Science and Public Health (A-06) Full Text

Expedited Partner Therapy (Patient-delivered Partner Therapy): An Update

Note: This report represents information on this subject as of June 2006.

Full Text

Council on Scientific Affairs (CSA) <u>Report 9 (A-05)</u> was prepared in response to Resolution 820 (I-04), which asked our AMA to: (1) encourage state licensing boards, medical societies, health and malpractice insurance carriers, and others to consider the demonstrated benefits of patient-delivered partner therapy (PDPT) when evaluating the appropriateness of this practice; (2) encourage continued research on expedited partner therapy (EPT) and other innovative strategies for sexually transmitted infection (STI) control; (3) encourage federal, state, and local governments to fully fund STI control programs; (4) support and encourage efforts by the Centers for Disease Control and Prevention to identify opportunities for increased use of PDPT; analyze existing and potential barriers to PDPT use; encourage use of PDPT in all appropriate settings; and establish model guidelines and recommendations for implementation of PDPT and other EPT strategies; and (5) notify appropriate medical societies, federal and state agencies, and malpractice carriers of its position on PDPT.

That Council report provided background information and scientific discussion on the issues surrounding EPT, described the AMA's collaborative efforts with the Centers for Disease Control and Prevention (CDC) on its thenpending white paper on EPT, and provided recommendations for consideration by the House of Delegates. These recommendations, as adopted at our AMA's 2005 Annual Meeting, asked the AMA to review and then support, if appropriate, the white paper on EPT to be issued by the CDC. The CDC released the final version of that paper in February 2006.

Data Source

• The CDC White Paper, *Expedited Partner Therapy in the Management of Sexually Transmitted Diseases*, released on February 2, 2006, and available online at <u>http://www.cdc.gov/std/treatment/EPTFinalReport2006.pdf</u> (PDF, 1398 KB, requires <u>Adobe® Reader®</u>).

Review of the CDC White Paper on Expedited Partner Therapy

The Council on Science and Public Health (CSAPH) reviewed the CDC's white paper on EPT and found it to be a well written and scientifically thorough analysis of the relevant issues. Many issues discussed in this paper are similar to those highlighted in CSA <u>Report 9 (A-05)</u>. The white paper systematically reviews the available literature on expedited EPT for the management of partners of persons with STDs. It also provides a balanced, thorough, and scientifically valid interpretation of the results from available research on the use of EPT. Significantly, it incorporates perspectives from two expert consultations, one that predominantly addressed the scientific evidence related to EPT, and a second that emphasized operational issues that will affect its implementation. The CDC intends the report to

serve as scientifically valid background information on EPT, providing evidence in support of anticipated future guidelines for the selective use of this therapy. The white paper is intended for use as a reference document by the CDC and by public health agencies, other organizations, interested individuals, and other partners in the public and private sector.

The <u>Appendix</u> to this report contains the executive summary of the CDC's white paper.

The CDC's Guidance for Expedited Partner Therapy

Expedited Partner Therapy in the Management of Sexually Transmitted Diseases concludes that EPT is at least equivalent to patient referral in preventing persistent or recurrent gonorrhea or chlamydial infection in heterosexual men and women, and in its association with several desirable behavioral outcomes. These conclusions support the following recommendations:

• **Gonorrhea and chlamydial infection in women**: EPT can be used to treat partners as an option when other management strategies are impractical or unsuccessful. Symptomatic male partners should be encouraged to seek medical attention, in addition to accepting therapy by EPT, through counseling of the index case, written materials, and/or personal counseling by a pharmacist or other personnel.

• **Gonorrhea and chlamydial infection in men**: EPT can be used to treat partners as an option when other management strategies are impractical or unsuccessful. Female recipients of EPT should be strongly encouraged to seek medical attention, in addition to accepting therapy. This should be accomplished through written materials that accompany medication, by counseling of the index case and, when practical, through personal counseling by a pharmacist or other personnel. It is particularly important that female recipients of EPT who have symptoms that suggest acute pelvic inflammatory disease (PID), such as abdominal or pelvic pain, seek medical attention.

• **Gonorrhea and chlamydial infection in men who have sex with men**: EPT should not be considered a routine partner management strategy, because data are lacking on its efficacy in this population, and because of a high risk of co-morbidity, especially undiagnosed HIV infection, in partners. EPT should only be used selectively, and with caution, when other partner management strategies are impractical or unsuccessful.

• Women with trichomoniasis: EPT is not recommended for routine use in the management of women with trichomoniasis, because of a high risk of STD co-morbidity in partners, especially gonorrhea and chlamydial infection. EPT should only be used selectively, and with caution, when other partner management strategies are impractical or unsuccessful.

• Syphilis: EPT is not recommended for routine use in the management of patients with infectious syphilis.

Conclusions

The CDC has systematically reviewed the scientific evidence on the implementation of EPT. Medical and scientific evidence supports the availability of EPT as an additional strategy for the treatment of heterosexual sex partners of patients who have been diagnosed with either chlamydial or gonorrheal infections. EPT should not replace other strategies, such as standard patient referral and provider-assisted partner referral, when they can be employed. However, the available evidence indicates that EPT is at least equivalent in efficacy to standard partner management for gonorrhea and chlamydial infection; that traditional partner management by public health agencies and health care providers for these STDs is limited in scope; and that the benefits of EPT outweigh the risks. Recipients of EPT should also receive written advice (and, when possible, personal counseling, such as by a pharmacist) that clinical evaluation is desirable in addition to EPT.

At this time, there are limited data to support the routine use of EPT for the management of women with trichomoniasis. Accordingly, EPT should be used with caution in these women, but it should remain an option when treatment of partners cannot otherwise be assured. There also are no data to support the use of EPT in the routine management of syphilis, which usually requires injection therapy and for which direct assistance with partner management is generally available from local or state public health departments. The efficacy of EPT in the management of any STD in populations of men who have sex with men, many of whose partners are likely to have undiagnosed HIV infection or other STDs, is also unknown. Data also is unavailable on the use of EPT in the management of patients with etiologically undefined clinical syndromes such as nongonococcal urethritis, mucopurulent cervicitis, and PID.

Numerous barriers, including that of missing opportunities to identify undiagnosed PID in the partner, legality of the practice of EPT, and payment for EPT, remain to be addressed in order to ensure that EPT can be successfully implemented throughout the United States.

RECOMMENDATIONS

The following statements, recommended by the Council on Science and Public Health, were adopted as by the AMA House of Delegates as AMA policy and directive at the 2006 AMA Annual Meeting:

- 1. The AMA supports the Centers for Disease Control and Prevention's (CDC) guidance on expedited partner therapy (EPT) that was published in its 2006 white paper, Expedited Partner Therapy in the Management of Sexually Transmitted Diseases. (**Policy**)
- 2.

The AMA will continue to work with the CDC as it implements EPT, such as through the development of tools for local health departments and health care professionals to facilitate the appropriate use of this therapy. (Directive)

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Also see the AMA's Infectious diseases Web site

Appendix: Executive Summary of the CDC's White Paper - *Expedited Partner Therapy in the Management of Sexually Transmitted Diseases*

Overview: Expedited partner therapy (EPT) is the practice of treating the sex partners of persons with sexually transmitted diseases (STD) without an intervening medical evaluation or professional prevention counseling. The usual implementation of EPT is through patient-delivered partner therapy (PDPT), although other methods may be employed. The available literature and selected unpublished studies were systematically reviewed, and this report provides background for the development of guidance on use of EPT as an option for partner management for selected STDs and patients.

Evidence: For STDs other than syphilis, partner management based on patient referral or provider referral has had only modest success in assuring partner treatment, largely attributable to limitations of available financial and personnel resources. EPT is believed to have been widely employed in women with trichomoniasis. Recent surveys document occasional use by many primary care providers in the management of patients with gonorrhea and chlamydial infection, and consistent use by a few. A retrospective case control study and two process-oriented analyses suggested that EPT holds promise as a partner management option. These studies contributed to CDC decisions to fund 4 randomized controlled trials (RCTs) designed to compare EPT with standard partner management approaches in men and women with gonorrhea, chlamydial infection, or trichomoniasis; and to assess behavioral predictors of treatment and reinfection.

Persistent or Recurrent Infection: The first RCT of EPT followed 1.787 women in 6 cities after treatment for chlamvdial infection. Recurrent infection was documented at follow-up visits 1 months and 4 months later in 12% of women randomized to EPT and 15% of those managed by patient referral (odds ratio [OR] 0.80, 95% confidence interval [CI] 0.62-1.05). The second RCT enrolled 2,751 men and women with gonorrhea or chlamydial infection from both public and private care settings in a single metropolitan area. Persistent or recurrent infection with either disease was found in 9.9% of subjects randomized to EPT and 13.0% of those who had standard patient-referral or provider-referral of their partners (OR 0.76, 95% CI 0.59-0.98). EPT was more effective in preventing gonorrhea at follow-up (OR 0.32, 95% CI 0.13-0.77) than chlamydial infection (OR 0.82, 95% CI 0.62-1.07). Chlamydial infection was present at follow-up in 7.6% of women who denied all sex since treatment, suggesting that a higher than expected rate of treatment failure accounted for some infections at follow-up. In the third available RCT, 977 men with symptomatic urethritis (principally gonorrhea and chlamydial infection) were randomized to EPT, patient referral, or patient referral enhanced by written education materials. Follow-up testing for gonorrhea and chlamydial infection 4-8 weeks later was accomplished in 37.5% of patients. Persistent or recurrent infection was found in 43% of subjects in the patient referral group (referent), 14% of men randomized to enhanced patient referral (OR 0.22, 95% CI 0.11-0.44, P<0.001), and 23% of men randomized to EPT (OR 0.38, 95% CI 0.19-0.74, P<0.001). For trichomoniasis, in an as yet unpublished RCT of 463 women randomized to the same interventions as the male urethritis trial, with 80% follow-up, the prevalences of infection 3-7 weeks later were not significantly different for patient referral (6%), enhanced patient referral (9%), or EPT (9%).

Behavioral Outcomes: The 4 available RCTs evaluated the association of EPT with index cases' reports of success in partner notification, confidence that their partners were treated, and sexual behaviors likely to predict reinfection. In 2 trials that enrolled male index cases, men randomized to EPT were equally or more likely to notify their partners than those randomized to the control strategies. Female index cases with chlamydial infection or gonorrhea who were randomized to EPT had either equivalent success or enhanced success in notifying partners compared with women randomized to standard partner management. In all 3 trials of gonorrhea or chlamydial infection, EPT was associated with at least equivalent and typically increased confidence by both male and female index cases that their partners had received treatment, including direct observation that their partners took medication. Two trials that addressed both gonorrhea and chlamydial infection found EPT to be associated with significantly reduced rates of sex with untreated partners at follow-up. The trichomoniasis trial showed general equivalence of EPT with desirable behavioral outcomes compared with standard patient referral

Cost Effectiveness: Preliminary economic analyses suggest that EPT is a cost-saving and cost effective partner management strategy.

Limitations: The data available to support EPT for chlamydial infection were derived in larger and geographically more diverse samples of patients than those for gonorrhea. Nevertheless, the evidence in favor of EPT, as measured by the rate of persistent or recurrent infection at follow-up, is stronger for gonorrhea than for chlamydial infection, perhaps due to a higher than expected rate of persistent chlamydial infection in women. This finding confounds the assessment of EPT in women with chlamydial infection. Assuring the treatment of infected men's female partners is a high priority to prevent ongoing transmission and community spread.

As for all RCTs, the extent to which the results of the available trials can be safely generalized to other populations and settings is not certain. Owing to modest sample sizes in some disease-specific patient groups, and varying effect sizes, not all outcomes of interest have been shown to be statistically significant. For example, further data are desirable on the use of EPT in male index cases. The available data do not support the routine use of EPT in the management of trichomoniasis, and no published data support the use of EPT for chlamydial infection or gonorrhea in men who have sex with men (MSM). Although substantial numbers of adolescents were included in the available trials, there is little experience in patients <18 years old.

Issues in Implementation of EPT: Among several pragmatic issues that will influence implementation of EPT as an STD prevention strategy, a dominant one is the possibility of undetected STD in partners. The potential for undiagnosed pelvic inflammatory disease (PID) is of concern when EPT is used to treat the female partners of men with gonorrhea or chlamydial infection. Therefore, EPT intended for female partners should be accompanied by warnings about the symptoms of PID and advice that women seek medical attention in addition to accepting treatment. Undiagnosed gonorrhea and chlamydial infection are common in the partners of women with trichomoniasis, and undiagnosed HIV infection and other morbidities have been found in many partners of STD-infected MSM.

The legality of EPT is uncertain in some states and overt statutory impediments exist in others; the practice is clearly legal only in a few states. The medicolegal ramifications may be uncertain in the event of adverse outcomes in the recipients of EPT. Other barriers include direct and indirect costs, including limitations on third-party insurance coverage; missed opportunities for prevention counseling of partners; risks of allergic reactions and other adverse drug effects; administrative barriers; privacy issues; and the attitudes and beliefs of health care providers and agencies about the practice.

Conclusions: Both clinical and behavioral outcomes of the available studies indicate that EPT is a useful option to facilitate partner management among heterosexual men and women with chlamydial infection or gonorrhea. The evidence indicates that EPT should be available to clinicians as an option for partner management, although ongoing evaluation will be needed to define when and how EPT can be best utilized. EPT represents an additional strategy for partner management that does not replace other strategies, such as standard patient referral or provider-assisted referral, when available. Along with medication, EPT should be accompanied by information that advises recipients to seek personal health care in addition to EPT. This is particularly important when EPT is provided to male patients for their female partners, and for male partners with symptoms. Existing data suggest that EPT has a limited role in partner management for trichomoniasis. No data support its use in the routine management of syphilis, and there is no experience with EPT for gonorrhea or chlamydial infection among MSM. Back to text

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