Expedited Partner Therapy for *Chlamydia trachomatis* Infection, *Neisseria gonorrhoeae Infection and Trichomoniasis:* Guidance for Health Care Professionals in Wisconsin

STD Control Section
Division of Public Health
Wisconsin Department of Health Services

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INTRODUCTION

On May 11, 2010, Governor Doyle signed into law *2009 Wisconsin Act 280*. This legislation became effective May 26, 2010 and it enables physicians, physician assistants, and certified advanced practice nurses to prescribe, dispense or furnish medication for sexually transmitted diseases (STDs) to partners of patients diagnosed with the STDs trichomoniasis, gonorrhea, and *Chlamydia trachomatis* infection without conducting a physical examination of the partner. This alternative STD treatment strategy, known as "expedited partner therapy" (EPT), allows a patient to deliver oral medication or a prescription for oral medication to a sexual partner without the partner first undergoing a medical evaluation.

While standard care for treating STDs includes testing, clinical evaluation and counseling by a clinician,[1] EPT is an alternative when a partner is unable or unlikely to seek care. The federal Centers for Disease Control and Prevention (CDC) concluded that EPT is a useful option to facilitate partner management, particularly for treatment of male partners of women with gonorrhea or *Chlamydia trachomatis* infection.[2] The CDC recommends the use of EPT to prevent persistent or recurrent infection when other management strategies are impractical or unsuccessful.

Act 280 does not pre-empt the requirement for local health departments (LHDs) in Wisconsin to conduct epidemiologic interviews and investigations of reportable STD cases. A copy of Act 280 is available at http://www.dhs.wisconsin.gov/communicable/STD/EPTfiles/09act280.pdf

The following guidance concerning EPT provides information regarding the most appropriate recipients, medications, and counseling procedures recommended to maximize patient and public health benefit while minimizing risk. However, this is guidance and each individual agency or health care provider must use their own judgment regarding what is best for their patient(s).

Multiple terms pertaining to specific infections can be used interchangeably. With rare exception, the following terms will be used throughout this document to achieve consistency:

- Chlamydia infection: the term representing *Chlamydia trachomatis* infection
- Gonorrhea: the term representing *Neisseria gonorrhoeae* infection
- Trichomoniasis: the term representing *Trichomonas vaginalis* infection

This Guidance was developed in consultation with the following agencies that permitted the Wisconsin Division of Public Health to adapt their EPT guidance: Illinois Department of Public Health, California Department of Public Health, and Minnesota Department of Health.

SUMMARY GUIDANCE FOR EXPEDITED PARTNER THERAPY (EPT)

EPT eligible partner: The sexual partner of a patient with a laboratory confirmed or suspected clinical diagnosis of trichomoniasis, gonorrhea or chlamydia infection, and who is unable or unlikely to seek timely clinical services.

First-choice partner management strategy: Attempt to notify and refer partners for complete clinical evaluation, STD/HIV testing, counseling, and treatment.

Recommended drug regimens for sex partners receiving EPT:
Patients diagnosed with trichomoniasis:

- Metronidazole (Flagyl*) 2 grams orally in a single dose

Patients diagnosed with chlamydia infection:

- Azithromycin (Zithromax*) 1 gram (500 mg tablets x 2) orally in a single dose

Patients diagnosed with gonorrhea:

- Cefixime (Suprax*) 400 milligrams orally in a single dose

PLUS

- Azithromycin (Zithromax*) 1 gram (500 mg tablets x 2) orally in a single dose

Number of doses allowed: One for each locatable sex partner during the 60 days prior to onset of symptoms or diagnosis of the original patient (or most recent sex partner if none identified in the previous 60 days).

Informational materials: A treatment information sheet must accompany each medication or prescription and must include clear instructions, warnings, and referrals (refer to specifics in *2009 Wisconsin Act 280*.) Information sheets from Wisconsin Department of Health Services (WDHS) can be found at:
Chlamydia - http://www.dhs.wisconsin.gov/publications/P0/P00197.pdf
Gonorrhea - http://www.dhs.wisconsin.gov/publications/P0/P00196.pdf
Trichomoniasis - http://www.dhs.wisconsin.gov/publications/P0/P00198.pdf

Important information includes:

- Warning about administering EPT to pregnant partners;
- Information about antibiotic and dosage provided/prescribed, and risk of drug allergies;
- Information about STDs, their treatment and prevention;
- Requirement of patient's abstinence from sex until seven days after treatment, in addition to until seven days after partner's treatment;
- Notification that sex partners receive testing for HIV infection and other STDs;
- Notification of risk to self, others, and public's health if the STD is not completely treated;
- The responsibility of the sex partner to inform his/her sex partners of the risk of STDs and importance of examination and treatment;
- Statement advising a person with questions about the information to contact his or her physician, pharmacist, or local health department.

Patient re-testing: Patients treated for gonorrhea or chlamydia infection should be re-tested three months after treatment to detect possible persistent or recurrent infection. Testing for recurrent infection should not occur until at least 45 days after treatment of the first infection has been completed. This is NOT a test of cure. Tests of cure are NOT recommended.

Liability: Wisconsin EPT legislation protects health care professionals and pharmacists providing EPT from civil and professional liability, except for willful and wanton misconduct.

*Use of trade names is for identification only and does not imply endorsement.

Summary provisions of *2009 Wisconsin Act 280*

Major provisions of the EPT legislation include the following:

1. Act 280 explicitly allows physicians, physician assistants, and certified nurse prescribers to dispense, furnish, or prescribe medication for EPT and pharmacists to dispense medication for EPT.

2. Liability for medical providers and pharmacists is limited as long as EPT is provided in accordance with the Act.

3. A prescription should be written in the partner's name (and address) or can also be written in ordinary bold-faced capital letters with "EXPEDITED PARTNER THERAPY" or "EPT" in place of a name/address, when the medical provider is unable to obtain the partner's name.

4. The Department of Health Services is required to prepare an information sheet. An information sheet is to be distributed to patients by medical providers and for use by the partner(s) receiving EPT. Materials will contain facts about trichomoniasis, gonorrhea, and chlamydia infection; treatment of these STDs; risk of drug allergies; and contact information for questions. To be in compliance with the Act, an information sheet must be distributed by the medical provider along with the EPT medication or prescription.

A copy of *2009 Wisconsin Act 280* is available at:
http://www.legis.state.wi.us/2009/data/acts/09Act280.pdf

A Wisconsin Legislative Council Act Memo which summarizes *2009 Wisconsin Act 280* is located on the web at http://www.legis.state.wi.us/lc/publications/act/2009/act280-sb460.pdf

BACKGROUND AND RATIONALE

Public health importance of trichomoniasis, gonorrhea, and chlamydia infection

Trichomoniasis, gonorrhea, and chlamydia infection are significant public health problems. The number of bacterial STDs reported in Wisconsin exceeds the number of all other reportable communicable diseases combined. In 2009, the Wisconsin Division of Public Health received reports of 20,895 cases of chlamydia infection and 5,206 cases of gonorrhea (trichomoniasis is not reportable in Wisconsin).[3] The CDC estimates that approximately half of all new gonorrhea and chlamydia infections occurring each year are undiagnosed and unreported.

Recurrent chlamydia infection or recurrent gonorrhea are associated with increased risks for pelvic inflammatory disease (PID), chronic pelvic pain, ectopic pregnancy, fetal death, and preventable infertility in women.[4] Untreated infections increase the risk for acquiring or transmitting HIV.[5] Within six months after treatment, persistent or recurrent infections occur in up to 11 percent of women and men treated for gonorrhea[6,7] and in up to 13 percent of patients treated for chlamydia infection.[8]

Trichomoniasis is an STD that is frequently asymptomatic and undiagnosed. It is the most common curable STD in young, sexually active women in the U.S. An estimated 7.4 million new cases occur each year among men and women.[9] Trichomoniasis can cause reproductive health and obstetric complications and can facilitate the transmission of HIV infection. Among men, it may cause as much as 5-10% of nongonococcal urethritis. Trichomoniasis often coexists with gonorrhea.[10]

Importance of partner treatment

To prevent repeat infections and other health complications associated with STDs and to prevent further transmission of infection in the community, sex partners of infected patients must be provided timely and appropriate treatment.

The main cause of recurrent sexually transmitted infections results from continued sexual contact with an infected partner. Patients with STDs have reduced risk for recurrent infection when their sexual partners are properly treated or are treated concurrently with the index patient.[11] Public health efforts to notify and treat sex partners are fundamental for syphilis control.[12] Because of the high burden of infection and limited public health resources for partner notification or provider referral, it is difficult for local health departments to provide proper or consistent investigation and partner notification for all cases of gonorrhea and chlamydia infection.[13] One alternative approach is patient (self) referral, where a health care provider counsels a patient about partner treatment and advises the patient to inform partners about their need for treatment.

There are several limitations to the effectiveness of patient (self) referral, including the patient's choice in notifying a partner and the partner's choice in seeking treatment. Asymptomatic partners often fail to seek care because they have no signs or symptoms of infection and they incorrectly assume they are not infected. Additionally, some partners may be uninsured and have limited access to medical care. These limitations require strategies other than patient referral to ensure appropriate therapy for sex partners.

An additional tool to aide in patient (self) referral is inSPOT, a peer-to-peer, Web-based, STD partner notification system. To use this tool, a patient needs internet access and then go to http://www.inspot.org/. The user can then select a city or state nearest him or her and click on "Tell Them." At this screen, the patient chooses from the assortment of cards to send to a partner, enters the e-mail address of each partner, selects the STD to which the partner has been exposed, enters their own e-mail address (or can send anonymously), and types an optional personal message. Upon receipt of the e-card, the partner clicks on it and is linked to a page containing disease-specific information.

The best practice for STD control and prevention is when sex partners are tested and prophylactically treated at the same time original patients are returning for treatment, rather than waiting until sex partner's test results are available. A cornerstone of disease intervention in STD control is prophylactic treatment of sex partners who were exposed during the 60 days prior to the original (index) patient's positive test or onset of symptoms for gonorrhea and chlamydia infection, thus preventing disease in partners by curing disease or eliminating incubating disease.

Effectiveness of EPT

Although research has shown that provider referral (where the health care provider notifies and refers sex partners for testing and treatment) is the most effective method for disease intervention in STD control, it is not always feasible.[17] Patient (Self) Referral is considered an alternative disease control measure.[17] Compared to patient (self) referral, EPT is associated with a higher likelihood of sexual partners being notified of their exposure and need for treatment.[11] EPT methods, when implemented properly, increase patients' reporting that all sexual partners were treated.[11]

Several research studies demonstrate that EPT is effective in facilitating partner notification and reducing recurrent gonorrhea and chlamydia infections among index cases:

- A meta-analysis that included five clinical trials found reduced occurrence of recurrent chlamydia infections and recurrent gonorrhea among patients receiving EPT compared with patients receiving standard partner treatment methods.[12]
- A randomized trial demonstrated that EPT was more effective than standard referral in reducing recurrent infection among patients with gonorrhea (3 percent versus 11 percent, $p = 0.01$), compared with those with chlamydia infection (11 percent versus 13 percent, $p = 0.17$).[14]
- A study of men with urethritis demonstrated EPT reduced recurrent infection rates from 43 percent (following patient self referral) to 23 percent .[15]
- A study of women with chlamydia infection found EPT reduced recurrent infection rates from 15 percent to 12 percent ($p = .10$).[16]

The *2009 Wisconsin Act 280* includes the option of using EPT for trichomoniasis. The CDC has not found sufficient evidence to support routine use of EPT for trichomoniasis and suggests cautionary use in managing women with trichomoniasis. The CDC recommends that EPT be an option when treatment of partners cannot otherwise be ensured.[11]

GUIDANCE FOR USING EPT IN WISCONSIN

When EPT is provided, clinicians should encourage partners to be tested promptly for other STDs because people with trichomoniasis, gonorrhea, and chlamydia infection are at risk of having other infections. Thus, patients most appropriate for EPT are those with partners who are unable or unlikely to seek prompt clinical services, due to partners that may:

- lack health insurance
- lack a primary health care provider
- be unwilling to seek medical care for an STD
- have other barriers to accessing clinical services

Providers also should assess the acceptability of EPT to both the patient and the partners receiving it.

Selecting appropriate recipients

EPT packets (including medication or prescription and an information sheet) are given to the original patient to be provided to the original patient's sex partners, with whom they have had sex in the 60 days prior to the onset of their symptoms or positive test.

EPT is clinically intended and indicated for the following partners:

a) Partners of original patients with a clinical diagnosis of sexually transmitted Chlamydia, gonorrhea or trichomoniasis confirmed by a positive laboratory test.

EPT should not be used for the following partners:

a) Partners of patients with syphilis.
b) Pregnant partners. They should not be considered for EPT and must be referred to their prenatal care provider or to another medical provider.

Providers should assess the partner's symptom status, particularly signs or symptoms indicative of a complicated infection, pregnancy status, and risk for severe medication allergies by a thorough questioning and discussion with the original patient. If the partner is reported to be pregnant, every effort should be made to contact her for referral to pregnancy services or prenatal care. For partners with reported or known severe allergies to antibiotics, EPT should not be provided.

EPT should be used cautiously among female partners and men who have sex with men (MSM):

- Female recipients of EPT who have reported signs or symptoms that suggest acute PID, such as abdominal or pelvic pain, should be referred to and seek medical attention.
- EPT should not be considered a routine partner management strategy among MSM, unless other partner management strategies are impractical or unsuccessful, because of insufficient data among this population and because of a high risk of undiagnosed HIV infection.[11]
- EPT is not recommended for routine use in the management of women with trichomoniasis, because of a high risk of STD co-morbidity in sex partners, especially gonorrhea and chlamydia.[11]

- EPT is not appropriate for patients, and their partners, who also have other STDs not covered by the EPT legislation, individuals who are suspected to have been sexually assaulted, children who are suspected to have been abused and other patients whose safety is in doubt.

Recommended treatment regimens

For Chlamydia:

- **Azithromycin (Zithromax) 1 gram** by mouth in a single dose (once).[18]
  Common side effects include headache, abdominal pain, diarrhea and vomiting.

Note: Single dose treatments are recommended for EPT delivery of either dispensed or prescribed treatment for chlamydia to achieve the greatest treatment compliance among partners. Therefore, multi-day doxycycline regime is not recommended for EPT. However, if a provider or clinic chooses to dispense or prescribe a seven day dose of doxycycline to treat chlamydia in partners, specific treatment and allergy warning information for such regimes should be provided by that clinician along with other information required in the EPT information sheet.

For Gonorrhea:

- **Cefixime (Suprax) 400 mg** by mouth in a single dose (once).[18]
  Common side effects include loss of appetite, nausea, diarrhea and vomiting.

PLUS [regardless if chlamydia is ruled out]:

- **Presumptive treatment for chlamydia co-infection: Azithromycin (Zithromax) 1 gram** by mouth in a single dose (once).[18]

Note: Fluoroquinolones (e.g., ciprofloxacin, ofloxacin, and levofloxacin) **should not** be used to treat gonorrhea. Consult with the current CDC STD Treatment Guidelines (http://www.cdc.gov/std/treatment/2010/default.htm) for alternative treatments.

For Trichomoniasis:

- **Metronidazole (Flagyl) 2-grams** by mouth in a single dose (once).
  Common side effects include dizziness, headache, diarrhea, nausea, stomach pain, and change in taste sensation or dry mouth.[18]

Note: Partners should be informed not to take metronidazole if they have consumed alcohol in the previous 12 hours, and to abstain from all alcohol for 24 hours following treatment.

Note: These are the **recommended** treatment regimens for EPT from WDHS and the CDC. Please consult with the current CDC EPT Review and Guidance, *EPT in the Management of STDs* (http://www.cdc.gov/std/ept/default.htm) and the current CDC *STD Treatment Guidelines* (http://www.cdc.gov/std/treatment/2010/default.htm) for alternative treatment regimens.[17, 18]

Options for Delivery of Drugs to Partners

1. Medication may be provided to the index patient to take to his or her partner(s).

2. Separate prescriptions shall be written for the index patient and his or her (their) partner(s).

3. If the clinician is unable to obtain the name of the patient's sex partner (s), the provider may write a prescription for "EXPEDITED PARTNER THERAPY" or "EPT." At the pharmacy, the pharmacist may ask for the patient's name and date of birth for the pharmacy records.

The patient should be given one full dose or prescription for each sex partner in the past 60 days. If the patient reports no sex partners in the past 60 days, EPT should be provided for the most recent sex partner.

In all situations, the patient must be given, per statute, a treatment information sheet that follows the provisions in the *2009 Wisconsin Act 280*. A basic information sheet will be developed by WDHS and available for distribution. The Treatment Information Sheet is to go along with each dose or prescription, for each partner who will receive EPT. Treatment Information Sheets must include certain provisions according to the *2009 Wisconsin Act 280*, which can be found at: http://www.legis.state.wi.us/2009/data/acts/09Act280.pdf. The treatment information sheets created by WDHS can be found at:
Chlamydia - http://www.dhs.wisconsin.gov/publications/P0/P00197.pdf
Gonorrhea - http://www.dhs.wisconsin.gov/publications/P0/P00196.pdf
Trichomoniasis - http://www.dhs.wisconsin.gov/publications/P0/P00198.pdf

Additional information that could be included on the information sheet:

a) Telephone numbers of clinical providers to contact for answers to their questions.
b) Follow-up information especially in areas with high rates of re-infection. The CDC recommends that all women with gonorrhea or chlamydia infection be re-tested three months after treatment. Providers are also encouraged to retest males three months after treatment.

Documentation: A note in the index patient's medical chart should document the number of partners who are being provided with EPT, the medication and dosage being provided, whether the partner is known to be allergic to any medications, and that educational information (the information sheet) has been included. Sexual partners do not require having a medical chart to be able to be provided with EPT.

Reporting

The *Sexually Transmitted Diseases Laboratory & Morbidity Epidemiologic Case Report* form (F-44243) includes fields to report whether or not EPT was provided and how many doses of each recommended treatment were provided for the index patient's sex partner(s). The number of doses of EPT is equal to how many treatment regimens that were provided for sex partners or prescriptions written for sex partners (there is a separate location on the report form to note the original patient's treatment). The F-44243 can be found at the WDHS website (http://www.dhs.wisconsin.gov/forms/F4/F44243.doc).

Considerations in using EPT

The following concerns have been raised regarding EPT:

- Concern: The medication could cause a serious adverse reaction, including an allergic reaction.
  Response: Adverse reactions to recommended EPT medications, beyond mild side effects, are rare.
- Concern: EPT may compromise the comprehensiveness of care provided to partners, particularly if it is used as a first-line approach for partners who would otherwise seek clinical services.
  Response: Clinicians should attempt to motivate patients to refer their partners for comprehensive health care, including evaluation, testing and treatment. Clinical services provide the opportunity to examine the patient, test for other STDs, HIV and pregnancy, confirm the diagnosis, ensure treatment, provide needed vaccinations and offer risk-reduction counseling and community referrals. These services constitute the standard of care for all partners of patients with a sexually transmitted infection. Ideally, partners who receive EPT will still access these clinical services.
- Concern: Misuse of the medication, waste if the medication is not delivered or not taken, and contribution to antibiotic resistance at the population level.
  Response: Currently, there is no evidence that EPT is misused or leads to increasing antimicrobial resistance. This risk is further minimized by recommending only single dose treatments for EPT.

Despite these concerns, the benefits of EPT in preventing the significant complications of untreated STDs outweigh the risks. Further, these risks may be mitigated through the use of patient education and written materials for partners that provide warnings and encourage visiting a health care provider.

Payment for Partner Medication

The index patient's insurance cannot be billed for the partner's medication (unless the partner is covered on the patient's insurance and the partner information is known). There is currently no state or federal funding to pay for EPT medication in Wisconsin.

Tools for implementing EPT in Wisconsin

- EPT partner information materials are available at
  - Chlamydia - http://www.dhs.wisconsin.gov/publications/P0/P00197.pdf
  - Gonorrhea - http://www.dhs.wisconsin.gov/publications/P0/P00196.pdf
  - Trichomoniasis - http://www.dhs.wisconsin.gov/publications/P0/P00198.pdf
- Adverse reaction reporting by telephone at 608-266-7365.
- For information regarding local efforts, please call your local health department's STD control program – for a list of LHDs visit http://www.dhs.wisconsin.gov.
- For a frequently asked questions (FAQ) sheet for pharmacists, visit the Department of Regulation and Licensing at http://drl.wi.gov/prof_practice_faq_detail.asp?prfaqid=1233&profid=35&locid=0

CDC EPT Practice Guidelines

In 2006, the CDC released the document *Expedited Partner Therapy in the Management of Sexually Transmitted Diseases; Review and Guidance*. [11] This and several other resources are available on the CDC website at http://www.cdc.gov/std/ept.

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