







Expedited Partner Therapy for Chlamydia Trachomatis Infection, Neisseria Gonorrhoeae Infection, and Trichomoniasis: Guidance for Health Care Professionals in Wisconsin



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Introduction

The CDC (Centers for Disease Control and Prevention) has concluded that Expedited Partner Therapy (EPT) is a useful option to facilitate partner management for patients with gonorrhea or chlamydia infection.² While standard care for treating Sexually Transmitted Infection's (STIs) 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 CDC recommends the use of EPT to prevent persistent or recurrent infection when other management strategies are impractical or unsuccessful.

Summary provisions of *2009 Wisconsin Act 280*

On May 11, 2010, Governor Doyle signed into law <u>2009 Wisconsin Act 280</u>. 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 STIs to partners of patients diagnosed with the STIs: trichomoniasis, gonorrhea, and chlamydia without conducting a physical examination of the partner. EPT is an alternative STI treatment strategy, that allows a patient to deliver oral medication, or a prescription for oral medication, to a sex partner without the partner first undergoing a medical evaluation.

Act 280 does not pre-empt the requirement for local health departments (LHDs) in Wisconsin to conduct epidemiologic interviews and investigations of reportable STI cases.

Summary provisions of <u>2009 Wisconsin Act 280</u> include:

- 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 and address when the medical provider is unable to obtain the partner's name.
- 4. The Department of Health Services (DHS) 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 STIs; 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.

This guidance discusses the most appropriate EPT recipients, medications, and counseling procedures recommended to maximize patient and public health benefit while minimizing risk. While this is the recommended guidance, each individual agency or health care provider must always use their best judgment regarding what is best for each individual patient.

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

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

Summary Guidance for Expedited Partner Therapy (EPT)

- **Patient's diagnosis:** clinical or laboratory diagnosis of chlamydia, gonorrhea, or trichomoniasis
- **First-choice partner management strategy:** attempt to notify and refer partners for complete clinical evaluation, STI/HIV testing, counseling, and treatment
- Most appropriate patients: those with partners who are unable or unlikely to seek timely clinical services
- 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:
 - Doxycycline 100mg orally BID x7 days
 - Azithromycin (Zithromax*) 1 gram orally in a single dose
 - Patients diagnosed with gonorrhea: Cefixime (Suprax*) 800 milligrams orally in a single dose
- **Number of doses allowed:** one for each 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*.)
- **Patient counseling**: abstinence until seven days after treatment and until seven days after partners have been treated to prevent reinfection
- **Patient retesting**: Treated patients should be retested after three months to detect possible persistent or recurrent infection.
- **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.

Background and Rationale

Public health importance of trichomoniasis, gonorrhea, and chlamydia infection

Chlamydia, gonorrhea, and trichomoniasis infections are significant public health problems. The number of bacterial STIs reported in Wisconsin exceeds the number of all other reportable communicable diseases combined. In 2018, the Wisconsin Division of Public Health received reports of 27,580 cases of chlamydia infection and 7,827 cases of gonorrhea (trichomoniasis is not reportable in Wisconsin).³

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

Trichomoniasis is an STI that is frequently asymptomatic and undiagnosed. It is the most common curable STI in young, sexually active women in the U.S. It is estimated that 3.7 million Americans have this infection. According to the CDC, only about 30% of people will have symptoms. Trichomoniasis can increase the risk of acquiring other STIs, including HIV. Additionally, it can cause preterm delivery in pregnant people and low birthweight babies. Per the CDC, sexually active people can get trichomoniasis by having sex without a condom with a partner who has trichomoniasis. In women, the infection is most commonly found in the lower genital tract (vulva, vagina, cervix, or urethra). In men, the infection is most commonly found inside the penis (urethra). During sex, the parasite usually spreads from a penis to a vagina, or from a vagina to a penis. It can also spread from a vagina to another vagina. It is not common for the parasite to infect other body parts, like the hands, mouth, or anus. It is unclear why some people with the infection get symptoms while others do not. People with trichomoniasis can pass the infection to others, even if they do not have symptoms. More information can be found on the Trichomoniasis – CDC Basic Fact Sheet webpage.

According to the CDC, the prevalence of *Trichomonas vaginalis* in the United States is 2.1% among women ages 14–59, and 0.5% among men based on a nationally representative sample of people who participated in NHANES 2013–2016. The following are other findings from this study:

- Prevalence was 9.6% for African American women, 1.4% for Hispanic women, and 0.8% for non-Hispanic white women.
- For men and women, increasing poverty level, lower educational level, unmarried status, and having been born in the U.S. are associated with *T. vaginalis* infection.

For women, younger age at first sex, greater number of sex partners, and a history of chlamydia infection in the past 12 months are associated with *T. vaginalis* infection. (<u>CDC - Trichomoniasis Statistics</u>).

Importance of partner treatment

To prevent repeat infections and other health complications associated with STIs, 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 STIs have reduced risk for recurrent infection when their sex partners are properly treated or are treated concurrently with the index patient. 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. 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.

<u>Tellyourpartner.org</u> is a confidential tool available to aid patients with telling their partners of their exposure. To use this tool, a patient would need to access the website. After accessing the website, the patient would need to select the button on the first page that says, "send a text." The site then walks the patient though five easy steps in order for them to anonymously notify their partners that they should be tested.

Effectiveness of EPT

Various factors including insufficient funds, numerous cases, and staffing make it difficult for health departments to interview all chlamydia and gonorrhea cases and are therefore prioritized to those at highest risk. According to the CDC, self-referral is the typical form of partner notification for persons with chlamydia infection and/or gonorrhea infection. The principal goal for gonorrhea and chlamydia infection is immediate treatment. Timely treatment of partners serves as a primary means of minimizing subsequent transmission. Randomized, controlled trials of single-dose oral therapy for both STIs have shown reduced rates of reinfection among index patients exposed to EPT compared with controls; approximately 20% for chlamydial infection and 50% for gonorrhea. A 2007 meta-analysis of trials revealed that these were statistically significant overall reductions. Use of EPT a was also associated with increased rates of index patient notification of partners and of partner treatment.

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 STIs, since 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 STI.
- 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, which includes medication or prescription and an information sheet, is given to the patient to be provided to the patient's sex partner(s). EPT should be provided to anyone with whom they have had sex in the 60 days prior to the onset of their symptoms or positive test. If the patient reports no sexual encounters in the last 60 days, EPT should be provided for patient's most recent sex partner.

EPT is clinically intended and indicated for 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:

- Partners of patients with syphilis. Partners who may have been exposed to syphilis must be referred for medical evaluation and management.
- Pregnant partners. A pregnant partner must be referred to their prenatal care provider or to another medical provider.

To the extent possible, providers should question the original patient to assess their partner's symptom status, and particularly check for signs or symptoms indicative of a complicated infection, pregnancy status, and risk for severe medication allergies. If the partner is reported to be pregnant, every effort should be made to contact the partner for referral to pregnancy services or prenatal care. For partners with reported or known severe allergies to antibiotics, EPT should not be provided.

EPT is not appropriate for:

 Partner(s) with a uterus that are reported to have signs or symptoms that suggest acute PID, such as abdominal or pelvic pain. These partners should be referred to and seek medical attention.

- MSM. EPT should not be considered a routine partner management strategy in this
 population because of a high risk of undiagnosed HIV infection¹¹ unless other partner
 management strategies are impractical or unsuccessful.
- Patients with trichomoniasis, because of a high risk of STI co-morbidity in sex partners, especially gonorrhea and chlamydia.¹¹
- Patients, and their partners, who also have other STIs 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

Full recommendation from the CDC:

Recommended Regimens for Chlamydial Infection Among Adolescents and Adults: Doxycycline 100 mg orally 2 times/day for 7 days

Alternative regimens (one or the other)

- Azithromycin 1 g orally in a single dose
- **Levofloxacin** 500 mg orally once daily for 7 days

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. More information available on the CDC's Chlamydial Infections webpage.

For gonorrhea

Full recommendation from the CDC:

Ceftriaxone 500 mg intramuscularly (IM) in a single dose for persons weighing <150 kg and 1 g ceftriaxone IM for persons weighing ≥150 kg

(If chlamydial infection has not been ruled out, treat for chlamydia with doxycycline 100 mg orally 2 times/day for 7 days.)

If ceftriaxone administration is not available or feasible, cefixime may be used:

• **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 (for example, ciprofloxacin, ofloxacin, and levofloxacin) **should not** be used to treat gonorrhea. Gonorrhea has progressively developed resistance to the antibiotic drugs prescribed to treat it. Following the spread of gonococcal fluoroquinolone resistance, the cephalosporin antibiotics have been the foundation of recommended treatment for gonorrhea. The emergence of cephalosporin-resistant gonorrhea would significantly complicate the ability of providers to treat gonorrhea successfully, since we have few antibiotic options left that are simple, well-studied, well-tolerated and highly effective. It is critical to continuously monitor antibiotic resistance in *Neisseria gonorrhoeae* and encourage research and development of new treatment regimens. Consult with the <u>current CDC STI Treatment Guidelines</u> for alternative treatments.

For trichomoniasis

Full Recommendation from the CDC:

Recommended Regimen for Trichomoniasis Among Women; Metronidazole 500 mg 2 times/day for 7 days

Recommended Regimen for Trichomoniasis Among Men: Metronidazole 2 g orally in a single dose

Alternative Regimen for Women and Men; Tinidazole 2 g orally in a single dose

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 DHS and the CDC. Please consult with the current CDC EPT Review and Guidance, <u>EPT in the Management of STDs</u> and the current CDC <u>STD Treatment Guidelines</u> for alternative treatment regimens.^{17, 18}

Options for delivery of drugs to partners

- Medication may be provided to the index patient to take to their partner(s).
- 2. A prescription may be provided to the index patient to take to their partner(s).

To write a prescription for EPT:

- Separate prescriptions shall be written for the index patient and their partner(s).
- 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 DHS and available for distribution.

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 the educational information (information sheet) has been included. Sex partners do not need a medical chart to be provided with EPT. The name of treated partner(s) should not appear in the index patient's chart.

Reporting

The <u>Sexually Transmitted Infections Laboratory & Morbidity Epidemiologic Case Report form (F-44243)</u> 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 or prescriptions were provided for sex partners (there is a separate location on the report form to note the original patient's treatment).

Considerations in using EPT

The following concerns have been raised regarding EPT:

Concern:	Response:
The medication could cause a serious adverse reaction, including an allergic reaction.	Adverse reactions to recommended EPT medications, beyond mild side effects, are rare.
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.	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 STIs, 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.
Misuse of the medication, waste if the medication is not delivered or not taken, and contribution to antibiotic resistance at the population level.	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 STIs outweigh the risks. Further, these risks may be mitigated using 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 will be available soon at the DHS website.
- Adverse reaction reporting: 608-266-7365.
- For information regarding local efforts, please call your local health department's STI control program for a list of LHDs visit <u>STD: Information for Health Care Professionals</u>.

CDC EPT practice guidelines

EPT is a useful option to facilitate partner management, particularly for treatment of partners who may otherwise go untreated for gonorrhea and *Chlamydia trachomatis* infections. This practice is proven to help prevent reinfection and curtail further transmission and complications of infection. <u>CDC hosts multiple resources regarding EPT on their website.</u>

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