

# **Expedited Partner Treatment (EPT) Toolkit for Implementation in Clinical Settings**

**GUIDANCE FROM THE MINNESOTA DEPARTMENT OF HEALTH**

## **Expedited Partner Treatment (EPT) Toolkit for Implementation in Clinical Settings**

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# Purpose Statement and Legal Disclaimer

The purpose of this document is to provide Minnesota health professionals comprehensive and clear guidance regarding the practice, clinical appropriateness, and implementation strategies for expedited partner therapy (EPT) in the state of Minnesota. **Legal advice is not provided within this document. Consultation with your and/or your organization's legal counsel is recommended if there are questions about the law, rules, statutes, and practices presented herein.**

## Introduction to Expedited Partner Therapy (EPT)

### Background and Rationale

Expedited partner therapy (also known as EPT, expedited partner treatment, or partner-delivered partner treatment) is a harm reduction strategy and is defined as:

***The practice of treating sexual partners of patients diagnosed with certain qualifying sexually transmitted infections by providing antimicrobial treatment and education for their partner(s) without a formal medical examination by a healthcare provider.***

The potential public health benefits of EPT include:

- To reduce the number of reinfections and persistent infections
- To reduce complications associated with untreated sexually transmitted infections (STIs)
- To decrease the probability of acquisition of other STIs, including HIV
- To decrease overall antimicrobial exposure and thus, slow the development of antimicrobial resistance (AMR)

To address the increasing incidence of preventable sexually transmitted infections and their complications, the use of EPT in Minnesota is endorsed by the following agencies and professional organizations that are a part of the multidisciplinary medical community:

- Centers for Disease Control and Prevention
- American Medical Association
- American Osteopathic Association
- American College of Obstetrics and Gynecology
- The Society for Adolescent Medicine
- American Academy of Pediatrics
- Minnesota Department of Health
- Minnesota Medical Association
- Minnesota Public Health Association
- Minnesota Pharmacists Association
- Minnesota Society of Health-System Pharmacists
- Minnesota Academy of PAs
- Minnesota Nurse Practitioners
- University of Minnesota College of Pharmacy
- University of Minnesota Medical School

While the ideal approach would all partners being promptly notified of their exposure(s) and being evaluated, tested, and treated with preferred treatment regimens, this may not always be feasible. **The CDC and/or MDH recommend partners of patients diagnosed with the following qualifying STIs are unable or unlikely to seek timely evaluation and treatment, EPT is recommended:**

- Chlamydia
- Gonorrhea
- Trichomoniasis\*

\* The 2021 CDC STI guidelines note “EPT might have a role in partner management for trichomoniasis, however no partner management intervention has been demonstrated to be superior in reducing reinfection rates.” Some, but not all states offer EPT for infections due to *T. vaginalis*. Due to the potential consequences of untreated *T. vaginalis* infections, MDH allows licensed providers to prescribe EPT for trichomoniasis in Minnesota.

## Impact on Antimicrobial Resistance

It is important to remember that recipients of EPT have a reasonable indication for antimicrobial therapy and that untreated STIs can have devastating consequences, many of which require more aggressive antimicrobial therapy such as pelvic inflammatory disease (PID). Concerns of EPT’s potential impacts on bacterial ecology and antimicrobial resistance have been raised, however recall above that one of the goals of EPT is to reduce the number of reinfections and persistent infections, both of which would require additional antimicrobial therapy. Considering the number of incident cases of STIs amenable to EPT each year and the already staggering number of antimicrobials prescribed, the potential impact of EPT on antimicrobial resistance would not be expected to be significant. As treatment recommendations for index patients continue to evolve, we anticipate that the regimens recommended for EPT will evolve as well. Optimizing the pharmacokinetics and pharmacodynamics of antimicrobials can play a significant role in deterring the development of resistance to antimicrobials. Further research to elucidate the optimal dose, frequency, and durations of the antimicrobials that are used in the treatment of both index patients and partners via EPT will be important to ensure any contribution to AMR by using EPT is minimized. It should be noted that drug resistant *Neisseria gonorrhoeae* has been identified as an urgent threat in the 2019 CDC Antimicrobial Resistance (AR) Threat Report<sup>1</sup>. EPT is one mechanism that might decrease the number of *N. gonorrhoeae* infections and thus the pathogen’s exposure to antimicrobials resulting in slowing the further development of resistance.

## Limitations of Evidence Supporting EPT

Published studies of EPT effectiveness primarily included heterosexual individuals. There is less certainty of the effectiveness of EPT due to limited evidence and complexity in certain aspects of care in the following populations:

- Men who have sex with men (MSM)
- Adolescents\*
- Pregnant women

\* Minnesota Statutes, Section 144.343 says, “[a]ny minor may give effective consent for medical, mental and other health services to determine the presence of or to treat pregnancy and conditions associated therewith, venereal disease, alcohol and other drug abuse, and the consent of no other person is required), see the section entitled “Providing EPT to Minors (under age 18) in Minnesota” below.

EPT is **permissible** in the above populations, however healthcare clinicians should make a good faith effort to educate the index patient and their partner(s) about the importance of timely medical evaluation, testing, and treatment using preferred treatment regimens, and use their best judgment to determine whether EPT is appropriate.

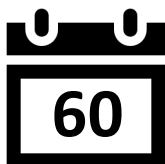
## MDH Antimicrobial Treatment Recommendations for EPT

### Limits on Providing EPT in Minnesota

The following partner quantity and time limits are imposed on EPT in Minnesota:



**ALL** sexual partners **within the last 60 days** may be offered EPT



**If no sexual partners in last 60 days:**

The **single most recent** sexual partner may be offered EPT

The Minnesota legislation regarding EPT (Minnesota Statutes, Section 151.37 Subd. 2(g)) was written in an effort to meet people where they are and accommodate various life situations, including scenarios in which the index patient may have a significant number of sexual partners (e.g., sex work). EPT may be offered to **all** of the sexual partners of the index patient within the 60 days preceding the diagnosis. There is no limit on the number of EPT prescriptions can be issued within this 60 day period. If the index patient reports not having any sexual partners within the last 60 days, EPT may be offered to the single most recent sexual partner.

### Antimicrobial Treatment Regimens for Partners of Patients Diagnosed with Qualifying Sexually Transmitted Infections

Infection	Preferred Regimen	Alternative Regimens	Safe in Pregnancy*
<b>Chlamydia</b>	Doxycycline 100 mg orally twice daily for 7 days	Azithromycin 1 gram orally for one dose	Azithromycin 1 gram orally for one dose†
<b>Gonorrhea</b>	Cefixime 800 mg orally for one dose	Cefpodoxime 400 mg orally for one dose	Either the preferred <u>or</u> alternative regimen

Infection		Preferred Regimen	Alternative Regimens	Safe in Pregnancy*
Trichomoniasis	Female	Metronidazole 500 mg orally twice daily for 7 days	Tinidazole 2 grams orally for one dose†	Metronidazole 500 mg orally twice daily for 7 days
	Male	Metronidazole 2 grams orally for one dose		

**\*ALL pregnant partners of index cases should be linked to prenatal care in addition to receiving the recommended antimicrobial treatment regimen(s) listed above**

†For pregnant persons who have contraindications for azithromycin being used for chlamydia EPT, amoxicillin 500 mg orally three times daily for 7 days is an acceptable alternative for EPT

‡For females in whom a 7 day course of metronidazole is not feasible for Trichomoniasis, 2 grams of metronidazole orally for one dose is an acceptable alternative for EPT



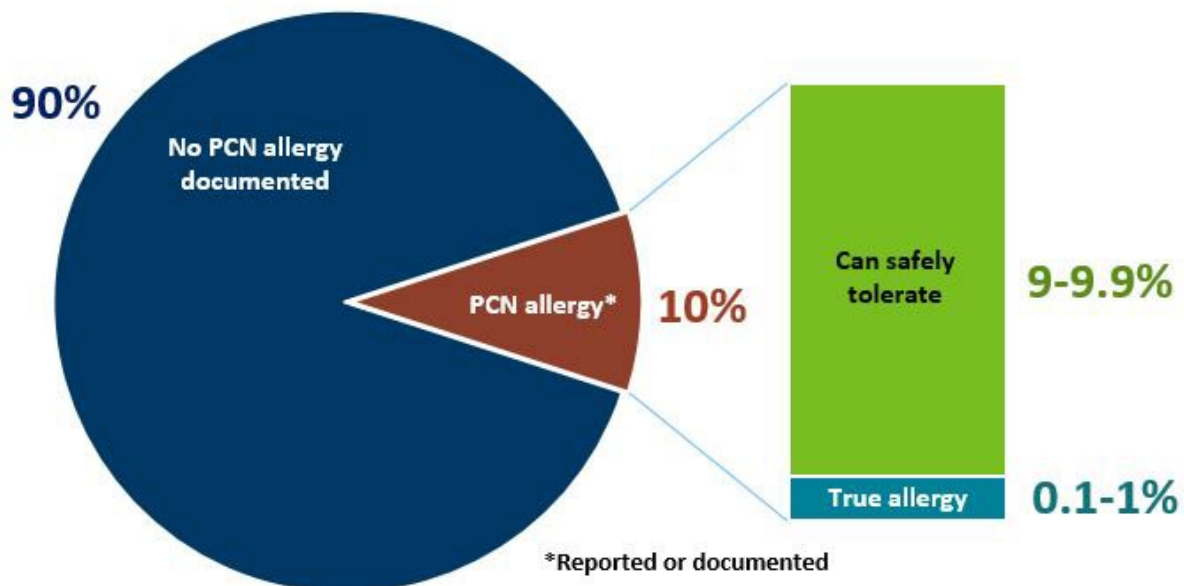
**All patients should be educated to abstain from ANY sexual activity for 7 days after FINISHING their treatment regimen(s) even if their symptoms improve**

For a printable version of the above table, refer to [EPT Regimen Quick Reference](#).

For recommendations on the management of index cases, please refer to the [MDH STD Information for Health Professionals page](#) and/or the [2021 CDC Sexually Transmitted Infection Treatment Guidelines](#).

## Penicillin and Other $\beta$ -lactam Allergies

At least 10% of patients in the United States have a penicillin allergy listed on their medical record, however when evaluated fewer than 1% of the population are truly allergic to penicillin<sup>2</sup>. Additionally, about 80% of patients with a true penicillin allergy confirmed by skin testing lose their sensitivity to the same penicillin after a period of 10 years<sup>2</sup>. Part of the discrepancy between reported allergy and actual allergy may be due to labeling expected side effects or intolerances as allergies and/or reporting of vague childhood reactions where details are unavailable. These seemingly small details can result in patients not being prescribed optimal antimicrobial treatment when they need it. The presence of a penicillin allergy on a patient's medical record has been associated with poor health outcomes including increased overall antibiotic exposure and use of healthcare resources, increased prevalence of methicillin-resistant *Staphylococcus aureus* (MRSA) and *Clostridioides difficile* (C. diff) infections, increased prevalence of vancomycin-resistant Enterococci (VRE), and even an increased cost to both inpatient and outpatient care<sup>3</sup>. Alternatives to penicillins and other  $\beta$ -lactam antibiotics typically have a broader spectrum of activity than is needed, are less effective, have more side effects, and selects for organisms with resistance to many antibiotics<sup>2</sup>.



It was previously thought that the  $\beta$ -lactam rings were the only explanation for cross-reactivity between the various  $\beta$ -lactam antibiotics. However, more recent research suggests that the R1 and R2 side chains contribute the most to immunological recognition and are most frequently responsible for cross-reactivity<sup>4,5</sup>. This information supports the idea that  $\beta$ -lactam allergies should not be considered a class effect<sup>6</sup>. The table below describes the  $\beta$ -lactams used in EPT (cefixime and cefpodoxime) and the other  $\beta$ -lactams that should be used with caution or avoided based on similarities in their R1 and/or R2 side chains. **Note in the table below that neither cefixime nor cefpodoxime share any side chains with any of the penicillins and only have side chain similarities to a select few cephalosporins.**

$\beta$ -lactam Antibiotic Used in EPT	USE WITH CAUTION if documented allergy to any of the following $\beta$ -lactams:	AVOID USE if documented allergy to any of the following $\beta$ -lactams:
Cefixime	Ceftaroline	Cefdinir
Cefpodoxime	Cefuroxime, ceftazidime	Cefditoren, cefotaxime, ceftriaxone, cefpime

## Allergies to Other Antimicrobials Used for EPT

### Macrolides

Despite the decades long history of macrolide use for a variety of infections due to their spectrum activity that includes gram positive, gram negative, and atypical bacteria, documented allergic reactions to any of the macrolides in the literature are very rare<sup>7</sup>. Azithromycin has largely replaced clarithromycin and erythromycin as the macrolide of choice owing to better pharmacokinetics and tolerability<sup>7</sup>. Since 1958, only 31 reports exist (including a total of only about 220 patients) detailing potential azithromycin allergic reactions ranging from mild itching to severe IgE-mediated or delayed hypersensitivity reactions<sup>8</sup>. In the context of countless courses of macrolides taken on an annual basis around the world, it is clear the risk for an allergic reaction to macrolides is incredibly low. There is limited information regarding



the potential cross-reactivity between the individual macrolides<sup>8</sup>. Consider using alternatives (if possible) or using azithromycin with caution in patients with well-documented severe reaction(s) to any of the macrolides, including fidaxomicin.

## Tetracyclines

Despite widespread use of tetracyclines since the 1940s, documented allergies to these antimicrobials have only very rarely been reported in the literature. Experience with these allergic reactions is limited to case reports and post-marketing surveillance and demonstrate an exceedingly rare incidence of immediate-type IgE-mediated hypersensitivity reactions to the tetracyclines<sup>9</sup>. Tetracycline is no longer widely available in the United States. Doxycycline is considered to be the best tolerated, least immunogenic, and most widely available tetracycline antibiotic. In contrast, minocycline appears to have more reports of non IgE-mediated dermatologic, pulmonary, and/or autoimmune adverse effects possibly owing to the metabolism of the parent compound into iminoquinone metabolites<sup>9</sup>. Most reports of adverse reactions to doxycycline and tetracycline, which do not get metabolized into iminoquinone derivatives, involve mostly mild non IgE-mediated dermatologic effects consisting of fixed erythematous drug eruptions<sup>9</sup>. Based on available information, it is clear the risk for an allergic reaction to tetracyclines, especially doxycycline, is incredibly low. Limited, conflicting evidence exists regarding potential cross-reactivity between the individual agents in the tetracycline class. Of note, an early concern regarding potential cross-reactivity between penicillins and tetracyclines has been disproven<sup>10</sup>. Consider using alternatives or using doxycycline with caution in patients with well-documented serious reaction(s) to other tetracyclines, glyclglycines (e.g., tigecycline), and/or aminomethylcyclines (e.g., omadacycline, eravacycline).

## Nitroimidazoles

Nitroimidazoles are a versatile class of anti-infectives that have activity against a variety of pathogens, including obligate and facultative anaerobic bacteria and various protozoa including *T. vaginalis*. Documented hypersensitivity reactions to nitroimidazoles are exceedingly rare and limited to a small number of case reports in the literature<sup>11</sup>. Single digit numbers of IgE-mediated reactions have been reported for both metronidazole and tinidazole. Other possible delayed hypersensitivity reactions are also limited to single digit case reports each and include contact dermatitis, erythematous drug eruptions, serum sickness-like reaction, Stevens-Johnson Syndrome, acute generalized exanthematous pustulosis, and a possible case of drug rash with eosinophilia and systemic symptoms (DRESS) syndrome<sup>11</sup>. Due to the limited therapeutic options and evidence of potential cross-reactivity between metronidazole and tinidazole via patch testing<sup>12</sup>, a patient or partner with well-documented severe reaction(s) to any nitroimidazole should be referred to a physician for evaluation of potential need for desensitization to metronidazole and would not be an appropriate patient for EPT. It should also be noted that more recent evidence had shed significant doubt on the concept that mixing alcohol with nitroimidazoles yields a disulfiram-like reaction and must be avoided<sup>13</sup>.

# Minnesota State Law Regarding Dispensing EPT

## Statutory Authority

**Statutory authority expressly AUTHORIZES EPT in the State of Minnesota** under Minnesota Statutes, Section 151.37, Subd. 2(g): Legend Drugs; Who May Prescribe, Possess. “Nothing in this chapter prohibits a licensed practitioner from issuing a prescription or dispensing a legend drug in accordance with the Expedited Partner Therapy in the Management of Sexually Transmitted Diseases guidance document issued by the United States Centers for Disease Control,” which references the most CDC’s most recent STI prevention and treatment guidelines ([found here](#)).

## Patient and Partner Privacy and Confidentiality

To the extent that EPT is part of the continuum of healthcare services and considered to be standard of care in Minnesota, the HIPAA Privacy Rule (45 CFR § 160.102) applies to most healthcare practitioners, including physicians, nurses, pharmacists, and public health workers, who treat patients and/or their sex partners through EPT. Even though many courts have specifically recognized that prevention of the spread of a communicable disease may justify limited sharing of patient health information (PHI), you should consult with your organization or legal counsel for legal advice on this and other HIPAA related provisions<sup>14</sup>. Moreover, MN Rule 4605.7700 requires that notwithstanding any previous report, a health care practitioner:

- “who has reason to believe a person having chlamydial infection, syphilis, gonorrhea, or chancroid has not completed therapy shall notify the commissioner immediately of that person’s name, address, and other pertinent information.”
- “who treats persons infected with chlamydial infection, syphilis, gonorrhea, or chancroid shall ensure that contacts are treated or provide the names and addresses of contacts who may also be infected to the commissioner. If known, persons named as contacts to a person with human immunodeficiency virus (HIV) infection, including acquired immunodeficiency syndrome (AIDS), shall be reported to the commissioner.”
- “shall immediately report to the commissioner the name, address, and essential facts of the case for any person known to have or suspected of having chlamydial infection, syphilis, gonorrhea, or chancroid who refuses treatment.”
- It should be noted that while MDH allows licensed providers to prescribe EPT for trichomoniasis in Minnesota, it is not currently a reportable disease in the state, so it is not included in MN Rule 4605.7700 referenced above

According to the HIPAA Privacy Rule (45 CFR § 164.522(a)(1)), patients or partners are permitted to request lawful restrictions of the disclosure of their PHI to their partner(s), however a practitioner is not obligated to agree to such requests. If the patient or partner requests that their diagnosis of a sexually transmitted infection(s) not be reported to local or state public health authorities despite the Minnesota reporting requirements described in MN Rule 4605.7040, the prescriber may not legally agree to this request because the protections of the Privacy Rule do not supersede state or local public health reporting requirements (45 CFR § 160.102).

## Providing EPT to Minors (under the age of 18) in Minnesota

Minnesota Statutes, Sections 144.341-347 allow minors to consent to certain types of health care services without parent or guardian permission. A provision exists specifically for the purposes of determining the presence of or treatment of sexually transmitted diseases (Minnesota Statutes, Section 144.343 Subd. 1), which says, “[a]ny minor may give effective consent for medical, mental and other health services to determine the presence of or to treat pregnancy and conditions associated therewith, venereal disease, alcohol and other drug abuse, and the consent of no other person is required. According to Minnesota Statutes, Section 144.335 Subd. 1(a) and the Minnesota Health Records Act (Minnesota Statutes, Section 144.291 Subd. 2(g)), pharmacists are not allowed to provide a minor’s health records to a parent or guardian in the event they are requested). However, Minnesota law (Minnesota Statutes, Section 144.346) allows a medical professional to inform the parent or legal guardian where, in their judgment, failure to inform the parent or guardian would seriously jeopardize the health of the minor. In these cases, best practices encourage a discussion with the minor about why confidentiality is being broken. Consult with your and/or your organization’s legal counsel with questions about these provisions.

### EPT Prescription Requirements

**1** Minnesota Sexual Health Clinic  
123 Main Street, Minneapolis, MN 55404  
612-555-5555

**2** Date: January 1, 2022

**3** Patient Name: EPT Partner AB

**4** DOB: n/a or 1/1/01

**5** Address: n/a or 111 EPT Drive, Minneapolis, MN 55404

**Rx** **6** **EPT**

**7** Doxycycline hyclate 100 mg tablets  
\*May sub monohydrate or capsules based on cheapest option in stock  
Sig: Take 1 tab bid x 7 days  
Quantity: 14 (fourteen) tablets / Refill: No

**8** Prescriber Signature: *Good Doc, MD*

**9** DEA or NPI: **1234567890**

Prescribers are required to follow the requirements for a valid prescription as specified in Minnesota Statutes, Section 151.01, Subd. 16(a). with few allowable exceptions for EPT as shown in the example above and explained in **bold** below:

1. The name of the location with address and phone number at which the EPT prescriber can be reached
2. The date the EPT prescription is issued
3. The name of the patient – **for EPT: if the partner’s information is available, this should be included otherwise as shown above, it is NOT required in order to fill and dispense**

an EPT prescription according to former Board of Pharmacy executive director. Generic dummy names (e.g., EPT Partner #1) are acceptable. The format of generic dummy names is flexible and will vary based on software capability. Prior to EPT legislation in 2008, the patient's name was required.

4. The date of birth of the patient – **for EPT: if the partner's DOB is available, this should be included otherwise as shown above, it is NOT required in order to fill and dispense an EPT prescription. Blank, "n/a", or generic dummy birthdays (e.g., 1/1/01) are acceptable.**
5. The address of the patient – **for EPT: if the partner's address is available, it should be included otherwise as shown above, it is NOT required in order to fill and dispense an EPT prescription. Blank, "n/a", or generic dummy addresses (e.g., 111 EPT Drive, Minneapolis, MN 55404) are acceptable.**
6. **For EPT: best practice is to indicate somewhere on the prescription that the intent is the issued prescription will be used for EPT, which would explain potentially missing information that would otherwise be required under the statute.**
7. The usual details about the drug being prescribed including full name of the drug including the drug strength, the "sig" or directions which should be as specific as possible to ensure the patient uses the medication properly, the quantity to dispense ideally written both numerically and alphabetically, and the number of refills – **for EPT: refills are not allowed.**
8. Signature of the prescriber (either manual if it is a written prescription or electronic if it is an electronic prescription)
9. The DEA is not required as none of the medications ordered for the purposes of EPT are controlled substances, however the NPI number of the prescriber is recommended as a best practice (but not required)

For a printable version of the above figure & information, refer to [EPT Prescription Requirements Quick Reference](#).

## Minnesota EPT Pharmacy Dispensing Laws

Pharmacies are strongly encouraged to process, dispense, and educate patients on EPT medications as outlined in MDH's EPT guidance document (Minnesota Board of Pharmacy News, October 2018). Former Executive Director stated "EPT prescriptions should be considered an order that may reasonably be dispensed by a Minnesota pharmacy, ideally with a name provided, but also without a partner name provided." **EPT has been legal in Minnesota since 2008, thus EPT is considered standard of care and should be dispensed from Minnesota pharmacies when prescriptions are issued**

(Minnesota Statutes, Section 151.37, Subd. 2(g)). Under MN Rule 6800.2250 Subp. 1(c), "[r]efusing to compound or dispense prescription drug orders that may reasonably be expected to be compounded or dispensed in pharmacies by pharmacists," (including EPT prescriptions) except as provided for in Minnesota Statutes, Sections 145.414 and 145.42 is unprofessional conduct and could result in disciplinary action through employers and/or the Board of Pharmacy.

For more information regarding EPT and how it affects Minnesota pharmacies, please see the Expedited Partner Therapy Toolkit for Minnesota Pharmacies.

## Prescribing EPT for Partners Enrolled in the Minnesota Restricted Recipients Program (MRRP)

The [Minnesota Restricted Recipient Program \(MRRP\)](#) is authorized by federal regulations and was developed to improve safety and the quality of care, as well as reduce costs for Minnesota Health Care Program (MHCP) recipients who have misused or abused services. MRRP recipients are required to receive health services only from their designated providers and/or facilities and pharmacies. As of 2021, there were approximately 2,000 Minnesotans enrolled in the program.

MRRP recipients may either be managed by the Minnesota Department of Human Services (DHS) or by managed care organization (e.g., Blue Cross Blue Shield, HealthPartners, UCare). Specific policies relating to the level of restriction and exceptions (e.g., in the event of the need for emergency care or if the recipient's designated provider is not available) vary by the entity that the recipient is managed through. **In general, MRRP recipients must get their EPT prescriptions filled at their restricted pharmacy.** Some entities may require the primary restricted provider to write the prescription while others may issue exceptions and/or allow other providers (e.g., an emergency department provider) to issue to the prescription.

The MN-ITS system shows the current restriction status of recipients and lists their designated provider, pharmacy, and facility(ies). Only eligible providers (which can include physicians, physician assistants, nurse practitioners, pharmacists, social workers, among others – for the full list of eligible providers, please visit the MN-ITS website) who are enrolled with MHCP and registered with the MN-ITS system maintain access. If an eligible and registered user is not readily available and you have questions relating to the care of an MRRP recipient at your pharmacy or institution, call DHS at 651-431-2648 or the patient's managed care organization.

## Prescriber Liability When Providing EPT

### Civil Liability and Standard of Care

Civil liability in a medical malpractice case is largely determined by the standard of care in the state in which a healthcare practitioner is licensed to practice. It is important to consult with your and/or your organization's legal counsel regarding liability when providing EPT because MDH cannot give legal advice. However, typically, whether EPT is considered to be within the standard of care is determined by<sup>14</sup>:

- The customary practices in the state, AND
- Whether the prescriber's actions are viewed as reasonable based on expert testimony and jury findings

Since 2008 when EPT became legal in Minnesota, it has become the standard of care for partners of index patients diagnosed with qualifying sexually transmitted infections. As evidenced by the guidance herein, including the broad endorsement of the practice by numerous organizations representing the multidisciplinary medical community in Minnesota, EPT is considered the standard of care in Minnesota. However, prescribers should check with their own and/or their organization's legal counsel on issues related to liability.

### Duty to Warn and the Learned Intermediary Doctrine

According to the CDC Legal/Policy Toolkit for the Adoption and Implementation of EPT, since STIs do not typically represent an "imminent danger" of "serious bodily harm," STIs do not

automatically trigger a legal requirement for duty to warn<sup>15</sup>. However, MDH cannot give legal advice and you should consult with your and/or your organization's legal counsel regarding this issue. A prescriber or pharmacist owes a special duty to patients when prescribing or dispensing prescription drugs to warn them of any potential complications, side-effects, or adverse reactions under what is known as the learned intermediary doctrine. Under this doctrine, in the event that the prescriber does not have the opportunity to directly discuss potential harms with the patient (which may occur in the practice of EPT when partner prescriptions are issued in the absence of a formal medical evaluation or meeting with the partner), the manufacturer of the drug assumes the duty to warn of various harms through prescription label requirements or other communications. However, in the case of the practice of EPT where the prescriber issues a specific prescription for the partner (even without identifying information or a medical evaluation), the transfer of liability may not apply, and the prescriber or pharmacist may have a duty to warn<sup>14</sup>.

Minnesota Rule 6800.0910 requires Minnesota pharmacists to consult with the patient or patient's agent or caregiver to inquire about the patient's understanding of the use of the drug, including the elements described in Subp. 2(a). However, if the index patient presents to the pharmacy and will deliver the EPT prescription to their partners, the index patient should be counseled on the partner's prescription. If the index patient or partner refuse the consultation procedure required by MN Rule 6800.0910 Subp. 2, the refusal must be documented as already required in MN Rule 6800.0910 Subp. 2(b). In this situation, best practice is to give the index patient or partner written education documents that can be referenced by the EPT recipient if there are questions. Additionally, a phone number in which the EPT recipient can contact a pharmacist should be emphasized. Patient friendly and translated materials are available on the Minnesota Department of Health EPT website and linked towards the bottom of this document.

## Can Obstetricians and Gynecologists Issue EPT Prescriptions for Male Partners?

Yes. A prescription order for EPT for a male patient issued by a board-certified obstetrician and gynecologist (OB/GYN) or another licensed medical professional practicing in the specialty is considered valid if the provider is appropriately licensed. This practice is encouraged by the American College of Obstetricians and Gynecologists (ACOG)<sup>14</sup>. Recall that one of the primary goals of EPT is to reduce recurrent and persistent infections (particularly amongst index patients), thus treating the male partner(s) of the index patient is actually an intervention to reduce the chance of recurrent and/or persistent infection in the index patient (e.g., the OB/GYN provider's patient).

## Liability Resulting from Adverse Reactions to Antimicrobials Used in EPT

This document gives prescribers and clinicians the tools they need to critically evaluate antimicrobial drug allergies. Additionally, the risk of adverse reactions to the antimicrobials used in EPT is minimal and can be managed with reasonable care and precautions (which are included in MDH's partner education documents). This results in a low threat of malpractice claims, especially in the setting of practicing the standard of care. It should be noted that a lack of reported judicial decisions does not mean that liability claims have not been filed or that they have not been settled outside of court<sup>14</sup>. One systematic review of professional liability when prescribing  $\beta$ -lactams for a patient with a known penicillin allergy suggests that clinicians are unlikely to be found liable when prescribing a penicillin or carbapenem for a patient with a known penicillin allergy but avoiding cephalosporins with similar side chains to the agent that



caused the allergy is likely legally prudent<sup>17</sup>. However, you should consult with your organization or legal counsel for legal advice.

## Specific EPT Implementation Strategies

### Patient and Partner Coaching and Education

#### General Strategies

Patients may experience anger, embarrassment, fear, and discomfort upon learning that they have an STI. This may be exacerbated when they realize they need to disclose this information to partners and encourage them to undergo testing and receive treatment. **Clinicians should inquire if the index patient has any safety concerns about disclosing this information to their partner(s).** If safety concerns are identified, refer to your institution's protocols. If no safety concerns have been identified and the index patient is willing and able to notify their partner(s) of their STI diagnosis, clinicians should reinforce the following:

- If the partner does not receive treatment, and they have sex again, there is a great likelihood that the patient will become reinfected
- If people are unaware they have the infection and/or do not get treated, they can develop serious health complications
- If a partner does not get treated, he/she can spread the infection to other partners, now or in the future
- Partners should seek a complete STI evaluation as soon as possible, regardless of whether they take the medication provided via EPT
- Partners who are or could be pregnant should seek care as soon as possible, regardless of whether they take the medication provided via EPT
- Index patients and partners should abstain from sex for at least seven days after completing their treatment and until seven days after all partners have been treated, to decrease the risk of recurrent infection
- Partners should be advised to seek clinical services for re-testing three months after treatment.
- The importance of *routine* STI screening to prevent a cycle of reinfections

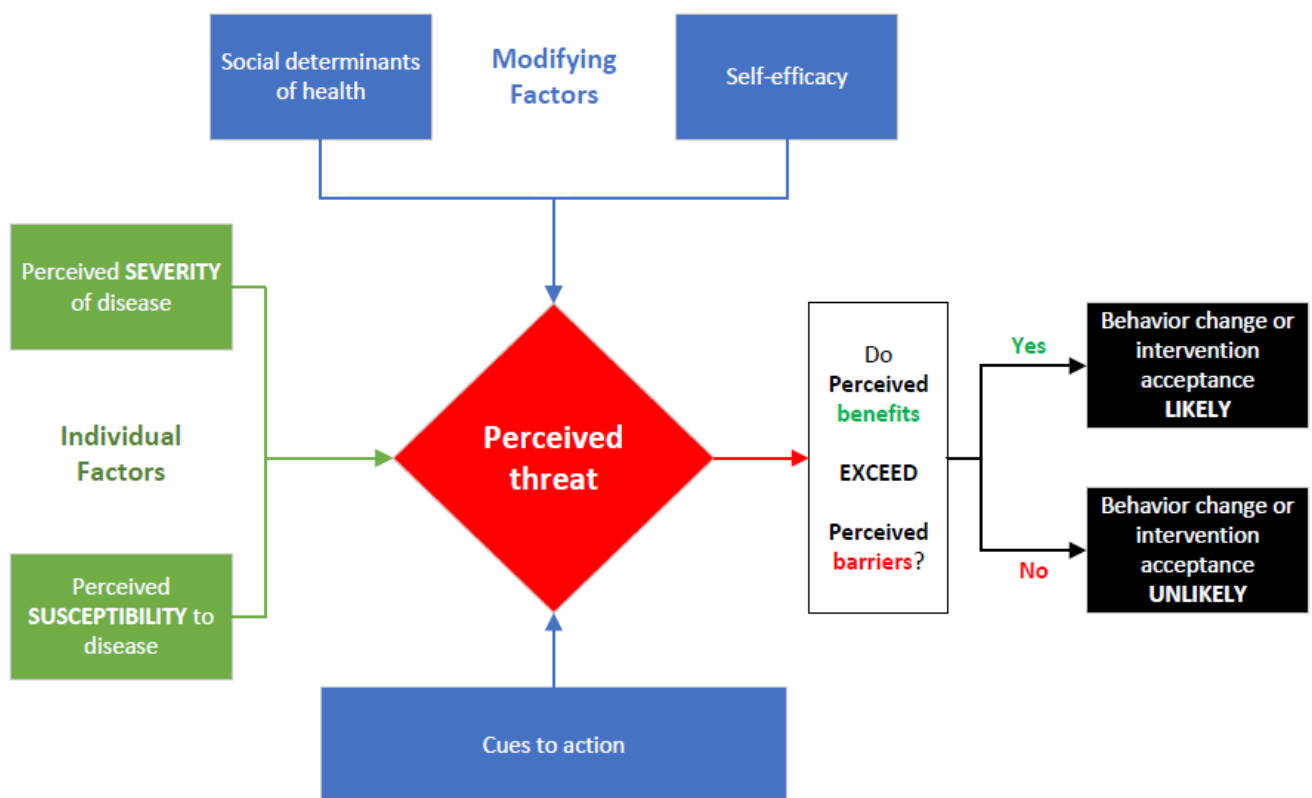
MDH provides partner education resources through our EPT website in English, Spanish, Somali, and Hmong. To accommodate all relevant information, our partner education documents fill one 8.5" x 11" piece of printed paper (both front and back sides). Clinical sites may use alternative formats, including smaller multi-fold cards, small cards with QR codes or web addresses, among other options to protect patient privacy and provide more discrete forms of partner education. Clinics are encouraged to create their own educational information as long as the required key elements are included (see MDH's partner education documents for more information).

#### A Modified Health Belief Model (HBM) Framework

The Health Belief Model (HBM) was developed in the 1950s by the United States Public Health Service (USPHS) in order to understand health-related behaviors regarding disease prevention strategies, screening tests, patient responses to symptoms, and compliance with medical

treatments. The HBM can provide a reasonable framework in which to understand behaviors and motivations for STI-related behaviors. It may also have a role in the coaching and education of index patients and partners by assisting clinicians in identifying what may be influencing their STI-related behaviors and possible acceptance of various interventions. The main principles of the HBM are that an individual's personal belief about the threat of an illness or disease and their belief about the effectiveness of the intervention can explain how likely the individual is to adopt certain health-related behaviors or interventions, such as routine STI testing or acceptance of EPT<sup>18,19</sup>. The constructs of the HBM are reviewed below.

### Modified Health Belief Model



**Individual factors** include:

- **Perceived severity of disease:** this concept refers to an individual's own perception of how serious contracting an illness or disease or leaving the disease untreated is and how it might impact their life. Severity may be measured physically (e.g., potential infertility), emotionally, and/or socially (e.g., stigma).
- **Perceived susceptibility to disease:** this concept refers to an individual's own perception of how likely they are to acquire an illness or disease. Susceptibility is often influenced by the individual's understanding of the disease, past personal experiences, visibility of the disease, among others.

**Modifying factors** include:



- **The social determinants of health:** the SDOH can drastically impact the perceived threat of an illness or disease.
- **Self-efficacy:** the concept of self-efficacy refers to an individual's confidence in their own ability to successfully perform a behavior or complete a task. This construct appears in many behavioral theories as it directly relates to whether a person adopts a desired behavior or health intervention.
- **Cues to action:** this concept refers to internal or external stimuli that influence the individual's perceived threat and thus, likelihood of accepting a health intervention or behavior. Internal cues to action typically include symptoms of disease. For example, a patient with urethral discharge and anal pain may have a higher perceived threat of disease and be more likely to accept EPT or referral to a clinic compared with someone who is asymptomatic. External cues to action are diverse in nature and can include advice from others (which may be inaccurate), social media, experiences of others, journal or media articles, etc.

These factors come together to form the individual's belief of a perceived personal threat from the disease. If the perceived benefits of a health intervention or behavior change (e.g., EPT or a visit to a clinic for testing, or acceptance of treatment) outweigh the perceived barriers in the context of the perceived threat, adoption of the intervention or behavior change is more likely. If they do not, behavior change is less likely, but the individual and modifying factors can be addressed to encourage adoption of desired interventions and/or behaviors.

## Health Professional Education

### EPT-Specific Education

In a recently published survey-based study of 623 healthcare providers who reported providing STI treatment in the past year in Minnesota<sup>20</sup>:

- Only 76% of the providers had heard of EPT prior to taking the survey
- Only 70% of the providers thought EPT was legal
- Only 37% of healthcare providers currently provide EPT as a prescription or direct medication
- Of those who do not currently provide EPT, 78% said they would provide the service under certain circumstances

This underscores the importance of healthcare professional education, visibility, and awareness of EPT as a public health program. Specific strategies for education of healthcare professionals may vary based on the practice site, academic setting, and/or role within the healthcare field and could include:

- Guidance from local and/or state departments of health (e.g., this document)
- EPT should be included in every healthcare professional program curriculum (e.g., nursing, medicine, physician assistant/associate, nurse practitioner, pharmacy, etc.)
- Outreach and partnerships with the Minnesota Department of Health STD/HIV/TB Section and/or local health departments
- Informational presentations about EPT at organizational conferences and meetings

- Partnerships with local academic institutions to create continuing education (e.g., CME, CEU, ACPE, etc.) opportunities via webinars or live lectures for healthcare professionals
- Consideration of required or elective electronic learning modules
- Inclusion of EPT as part of an on-boarding or orientation checklist for new employees
- Required attestation of commitment providing equitable healthcare via vision statements, mission statements, and/or official policy that includes a provision for EPT
- Expand responsibility for STI awareness and care by appointing an EPT champion at each practice location or institution
- Encourage healthcare professionals who provide EPT services and/or learners (e.g., students, residents, fellows) to share knowledge and experiences or educate others

## Education Regarding Taking a Meaningful Sexual History

An important part of the evaluation of a patient with concern for a sexually transmitted infection should involve discussing specific risk factors, behaviors and practices, prevention measures, past history of STIs, and pregnancy intention however these conversations can be awkward or embarrassing for both patients and providers and thus ignored or skipped. Following a standardized framework can be helpful to ensure providers elicit meaningful information from their patients without getting too distracted by the emotions that may be produced by the discussion. One of the most common frameworks for taking a sexual history is the “5 P’s” which include:

- Partners
- Practices
- Protection from STIs
- Past History of STIs, including HIV
- Pregnancy

Useful resources for clinicians looking to improve their ability to take a sexual history include:

- The CDC National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention provides an in-depth guide to taking a sexual history that is based on the “5 P’s” which can be found [here](#)
- The California Prevention Training Center provides an example provider-patient interaction in which a physician uses the “5 P’s” framework to take a comprehensive sexual history which can be found [here](#)
- The New York City Department of Health and Mental Hygiene adapted a quick reference for taking a sexual history using the “5 P’s” framework which can be found [here](#)

## Delivery of EPT Medications

Various methods exist to get prescription(s) or medication(s) into the hands of EPT recipients and include:

- Medication packages that can be sent with the index patient to give to their partner(s) from the clinic or practice site (see the section on Dispensing EPT from Clinics below)

- Written, electronic, verbal, or faxed prescriptions for EPT recipients may be sent directly to any Minnesota pharmacy for the EPT recipient to pick up (if desired pharmacy is known)
- Written prescriptions may be given to the index patient for the identified number of partners who are deemed unlikely to seek timely care for evaluation, testing, and treatment so that they may give the prescriptions to their partner(s) who can then take the prescription to the pharmacy of their choosing
- Medication delivery services offered through various community pharmacies can be considered for EPT recipients who do not have reliable or available transportation if sufficient partner information is available (e.g., address)

## Utilizing Electronic Medical Records to Facilitate EPT

Most healthcare systems that provide patient care utilize an electronic medical record (EMR) that has technology that can be leveraged to ensure clinicians who are providing EPT services can do so more efficiently and appropriately. Optimizing the EMR may even reduce barriers and encourage otherwise hesitant clinicians to start incorporating EPT into their practice.

Potential ways that EMRs and developers can be used to facilitate the practice of EPT include:

- Utilize best practice alerts (BPAs) including pop-up alerts to identify index patients who should be educated about their sexually transmitted infection and the likelihood that their partner(s) may seek medical evaluation, testing, and treatment
- Create templates that populate certain prompts in progress notes meant to guide clinicians through the sexual history, or other aspects of sexual health care, which may help identify situations in which EPT should be offered
- Add information about EPT to after visit summaries (AVS) that are typically reviewed with the patient prior to discharge from the clinic or emergency department
- Create editable letter-like template that can be printed with the AVS, similar to a work or school absence note
- Build order sets or clinical pathways within the EMR to ensure appropriate EPT dosing based on the STI being treated and any relevant concomitant conditions (e.g., pregnancy)
- Utilize forums and/or message boards moderated by EMR developers to share workflows, tools, forms, templates, code, and/or infrastructure to disseminate information about how to leverage the EMR to optimize the practice of EPT

## Dispensing EPT from Clinics

EPT treatment courses would be allowed to be dispensed from the clinic setting if the drugs were bought and packaged for dispensing by the clinic under the practitioner dispensing rules in MN Rules 6800.9950-9954. Clinics engaging in practitioner dispensing of EPT treatment must follow applicable drug storage (MN Rule 6800.9951), dispensing (MN Rule 6800.9952), and labeling (6800.9953) requirements. The clinics must also keep the following information on file and readily retrievable for a period of at least 2 years:

- A record or invoice of all drugs received for purposes of dispensing to patients
- A prescription record of the drugs dispensed, filed by prescription number or date, showing the patient's name and address (the aforementioned exceptions regarding this information

for EPT applies), date of the prescription, name of the drug, strength of the drug, quantity dispensed, directions for use, signature of the provider

- Refills should not be provided for EPT prescriptions as to avoid potential insurance fraud and/or encourage follow-up, so MN Rule 6800.9954 Subp. C does not apply
- Patient profile requirements under MN Rule 6800.3110

**Note:** A clinic may not contract with a pharmacy to prepack medications unless the pharmacy is registered as a manufacturer as outlined in MN Rule 6800.1400. If the pharmacy is not registered as a manufacturer, the pharmacy that is prepacking the medication must also dispense the medication according to the Board of Pharmacy. No rules prohibit clinics from prepacking medications as long as the above-mentioned practitioner dispensing rules are followed. For additional questions, please call the Minnesota Board of Pharmacy at (651) 201-2825.

## Developing Standing Orders, Protocols, and/or Collaborative Practice Agreements

An important consideration in expanding the availability of EPT is through standing orders, protocols, and/or collaborative practice agreements (CPA) which allow more accessibility to services and improve equity in the delivery of EPT services while allowing and empowering healthcare professionals (including but not limited to nurses, pharmacists, laboratory personnel, medical students and/or others) to practice “at the top of their license.” After development of standing orders, protocols, and/or collaborative practice agreements, it is recommended that your personal and/or your organization’s legal counsel be consulted to review the documents prior to implementation.

Under a standing order or protocol, healthcare professionals may perform functions that are related to specific conditions or procedures that have been predetermined by a prescriber. In effect, standing orders are indeed prescriber orders that are being carried out by other healthcare professionals when those predetermined conditions have been met. Protocols vary slightly from standing orders. These protocols may be specific to an institution or may be instituted statewide by an authorized body of the state and are typically initiated by the prescriber.

CPAs are voluntary agreements that create a formal practice relationship between a healthcare professional that does not typically prescribe with a prescriber, whereby the prescriber delegates certain functions and responsibility to the other professional which can include ordering laboratory tests and/or initiating or adjusting drug therapy. The exact specifications of a CPA may vary depending on the type of professional providing the services and the state they are practicing in. CPAs can be specified to apply to only certain patients or a more generalized practice model. Certain credentialing or privileging requirements may be recommended or required.

- For example, certain requirements for CPAs are delineated for pharmacists in the Pharmacy Practice Act (Minnesota Statutes, Chapter 151). An example of a CPA that is being used in Minnesota to improve access to education and prompt and appropriate treatment of STIs, including offering EPT includes pharmacists working in the emergency department setting. These pharmacists, who often have at least one year of post-graduate residency training, enter a CPA with the medical director of the emergency department, which allows them to follow-up on various microbiology results, inform the patient of these results, provide

education, and prescribe antimicrobial treatment (including EPT, if appropriate) independently.

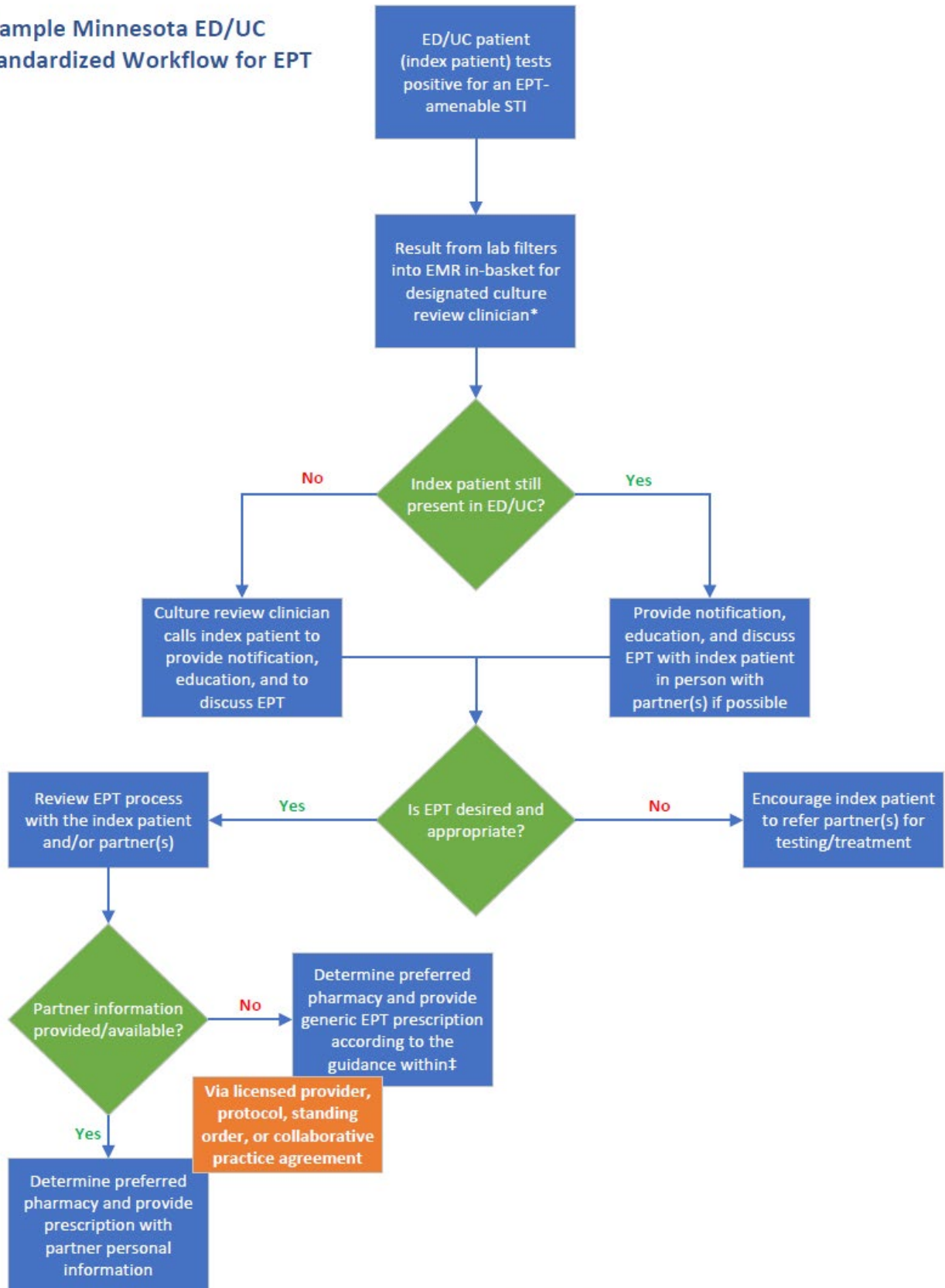
## Emergency Department and Urgent Care Strategies

Emergency departments (ED) and urgent cares (UC) play a unique role in public health. These facilities are available to patients without appointments, many with extended hours or 24/7 staffing thus play an important part in providing health care to patients without access to other types of medical services. Although the primary purpose of these facilities is not to provide preventive or population health services, the reality is that they are uniquely positioned to address health disparities caused by the social determinants of health in part by minimizing the spread of the communicable diseases that often disproportionately affect minoritized groups (including sexually transmitted infections).

Examples of implementation strategies for use in EDs and UCs that facilitate efficient and appropriate use of EPT:

- Provide education to ED and UC providers regarding the contents of this toolkit, specifically as it relates to liability and prescription requirements
- Design department specific EPT processes (example below)
- Designate a culture review clinician (e.g., pharmacist, nurse, physician, physician assistant, nurse practitioner, etc.) for timely review of microbiology results, including STI results to ensure prompt notification, education, and assessment for the need for EPT with the index patient
- Create standing order, protocol, or collaborative practice agreement with the designated culture review clinician(s)
- Develop standardized STI and EPT education points to be shared with index patients and their partner(s), if available
- Partner with a local pharmacy to ensure they have recommended antimicrobials for EPT as part of their standard stock
- Utilize clinical pharmacists, the hospital or system-level antimicrobial stewardship program, and information technology to implement an EPT order set
- Consider applying for institutional or foundational grant funding to cover the cost of EPT dispensed at your facility's discharge pharmacy, if applicable

**Example Minnesota ED/UC  
Standardized Workflow for EPT**



\*The designated culture review clinician may be any appropriate licensed health professional (e.g., pharmacist, RN, physician, PA, NP, etc.)

†Education for the index patient should be standardized to ensure consistency, though can be modified based on needs of the patient

‡EPT prescriptions without partner name, DOB, address allowed per former BOP director Dr. Cody Wiberg & Minn Stat. § 151.37 Subd. 2(g)

## **EPT Patient Education and Clinician Reference Documents**

[Link to printable version of recommended antimicrobial treatments quick reference](#)

[Link to printable version of EPT prescription requirements quick reference](#)

[Link to partner education documents](#)



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