Guidelines for the Treatment of Chlamydia and Gonorrhea Cases and Exposed Sexual Partners by Health Department Staff in Non-Clinical Settings

Developed by the California Department of Public Health (CDPH) Sexually Transmitted Diseases (STD) Control Branch and the California STD Controllers Association

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Introduction

This document is intended to provide guidance for the practice of field-delivered treatment (FDT) for chlamydia (CT) and gonorrhea (GC). FDT is the delivery of either medication or a prescription for medication by trained health department staff in non-clinical settings, under the oversight of a health department physician.

Executive Summary

These guidelines provide information about patients, procedures, and medications for field-delivered treatment (FDT) for chlamydia (CT) and gonorrhea (GC), recommended to maximize patient and public health benefit while minimizing risk.

- An appointment with a clinician at which the patient or partner(s) can receive testing and care for all STDs and HIV is the preferred management strategy for CT and GC treatment.
- FDT should only be used when a clinic appointment cannot be made or would not be attended in a timely manner.
- Appropriate patients for FDT are those diagnosed with CT or GC, or their partners, who have not been treated or have been incompletely or incorrectly treated.
- Recommended drug regimens are:
    - CT: azithromycin (Zithromax*) 1 gram orally once
    - GC: cefixime (Suprax*) 400 mg orally once[1],
      PLUS azithromycin (Zithromax*) 1 gram orally once
- Educational materials must accompany medication.
- Patients should be counseled to abstain from sexual activity until seven days after treatment and until seven days after their partners have been treated.
- All patients diagnosed with CT or GC should be re-tested three months after treatment.
- Patients should seek medical care for adverse reactions from a qualified clinician. After the patient has been assessed, local health jurisdictions should report all adverse reactions to the STD Control Branch at 510-620-3400.

[1] Ceftriaxone 250 mg intramuscular injection plus azithromycin 1 g orally is the recommended regimen for GC. Cefixime 400 mg orally can be used in place of ceftriaxone where an oral dose is needed, as is the case for FDT. Oral treatment may not cure pharyngeal GC in all patients.

Background and Rationale

Appropriate and prompt treatment of persons with STDs is critically important in preventing health complications and interrupting disease transmission in the community. Many STD patients and partners face significant barriers to accessing needed clinical services and thus may remain untreated for their infections. Providing medication or a prescription for medication in non-clinical settings offers a means to overcome some of these barriers and ensure more timely treatment.

The purpose of these guidelines is to support local health departments in California to take action to ensure that STD patients and partners receive effective and timely treatment.

These guidelines focus on CT and GC because (1) these infections are of public health importance and are reportable, (2) treatment can be accomplished with oral medication, and (3) the benefits of treatment outweigh the risks, particularly in patients who would not otherwise receive treatment.

STD Controllers are encouraged to collaborate with their local health officers to determine appropriate control measures.

Guidance for FDT

An appointment with a clinician at which the patient or partner(s) can receive testing and care for all STDs and HIV is the preferred management of patients with a diagnosis of CT or GC. FDT is a tool for ensuring treatment that *should only be used when a clinic appointment cannot be made or would not be attended in a timely manner*.

Patients or partners who receive FDT for GC with the above recommended regimen (cefixime 400 mg orally once PLUS azithromycin 1 g orally) are receiving suboptimal therapy. First line therapy for GC is ceftriaxone 250 mg intramuscular (IM) injection PLUS azithromycin 1 g orally. In general, oral cephalosporins are less effective in eradicating pharyngeal GC infection. If the patient or partner receiving FDT is at risk for pharyngeal infection (performing oral sex on a man), then they should be informed that oral treatment may not cure pharyngeal GC in all patients, and a referral for STD testing should be provided. Clinical referrals and educational materials are a critical component for all persons receiving FDT.

Another way to manage treatment for partners who cannot or will not attend a clinic appointment is patient-delivered partner therapy (PDPT); guidelines for

patient-delivered partner therapy are available on the CDPH STD Control Branch website (www.std.ca.gov).

Definition

FDT is defined as the delivery of oral medication or a prescription for medication by trained health department field staff under the supervision of a health department clinician. FDT is an appropriate option for:

PATIENTS diagnosed with CT or GC in a health department, private or other non-health department clinic who were unable or unlikely to seek treatment in a timely fashion by

- not returning for treatment, **or**
- not following the treatment regimen or vomiting soon after treatment and not visiting a clinician for retreatment.

OR

PARTNERS who

- have been sexually exposed to the patient within the period of infection,
- have not been diagnosed with CT or GC in a health department, private, or other non-health department clinic, **and**
- who are believed by the field staff to be incapable of seeking prompt evaluation and treatment.

Potential coinfection (with syphilis, HIV, or other STDs) is addressed in Appendix A.

Notification of the diagnosing clinician

The diagnosing clinician should be notified that the health department is initiating FDT. There is no further need to contact providers if the request for follow-up was initiated by the clinician, or for ongoing referrals for health department follow-up, e.g., routine follow-up for cases diagnosed but not treated in jails.

Components of a FDT patient encounter

When conducting FDT, each encounter should include:

- education of the patient regarding disease and treatment,
- risk-reduction and safer sex counseling,
- assessment of contraindications (see below),
- documented consent to treatment (contact and patient interview materials can be found in Appendices B and C),
- referral to a local clinic or health department for other STD and HIV testing, even if the patient takes the oral medications by FDT, **and**
- recommendation for repeat testing at three months for reinfection.

Recommended FDT

CT treatment for PATIENTS or their PARTNERS:

- oral medication for CT (Azithromycin 1 g)
  or
- a prescription for this medication

GC treatment for PATIENTS or their PARTNERS:

- oral medications for GC (Cefixime 400 mg plus Azithromcyin 1 g) **or**
- prescriptions for these medications
- all patients and their partners need dual therapy (two medications) regardless of the patient's CT test results

Other treatments may be authorized locally.

Contraindications to FDT

FEMALES

- Lower abdominal pain
- Fever
- Pain with sex
- Indication of severe allergy (e.g., anaphylaxis, Stevens Johnson syndrome, toxic epidermal necrolysis) to:
  - penicillin and/or cephalosporins, including cefixime for patients in need of treatment for GC
  - macrolides, including azithromycin, for patients in need of treatment for CT or GC

  (allergy risk and other drug information is detailed in Appendix E)
- Serious illness such as heart, liver, or kidney disease
- Pregnancy: Pregnant women should be in prenatal care, and treatment should be provided by the prenatal care provider. If the patient is unable

or unwilling to access prenatal care, the case should be reviewed by a health department physician before treatment.

MALES

- Pain or swelling in testicles
- Fever
- Indication of severe allergy (e.g., anaphylaxis, Stevens Johnson syndrome, toxic epidermal necrolysis) to:
    - penicillin and/or cephalosporins, including cefixime for patients in need of treatment for GC
    - macrolides, including azithromycin, for patients in need of treatment for CT or GC

  (allergy risk and other drug information is detailed in Appendix E)
- Serious illness such as heart, liver, or kidney disease

National guidance can be found in Appendix D, other questions and answers in Appendix F, and the bibliography in Appendix G.

Appendices

A. Co-infection

B. Suggested template for policies and procedures

C. Patient interview materials guidance, including sample consent form

D. National guidance

E. Allergy risk and other drug information

F. Questions and Answers

G. Bibliography

Appendix A.

CO-INFECTION

Every effort should be made to provide rapid HIV and syphilis testing to patients and partners who have not been tested for these infections.

It is possible that a partner eligible for FDT may have an undiagnosed STD. Research evaluating the risk of missed infections for PDPT (as reviewed in Golden, *Clin Infect Dis 2005;* 41:630-633) suggests that the probability of additional (other than CT or GC) co-infections in heterosexual partners of patients infected with CT or GC is small, although not nonexistent.

These data suggest that the benefits of FDT outweigh the risk of potential missed co-infection in these populations. However, 20 percent of partners of STD clinic attendees infected with GC were also infected with trichomonas in one study using nucleic acid amplification testing to assess trichomonas infection (Kahn et al., *Sex Transm Dis* 2005, Apr; 32 (4):260-264). Another study reported an HIV infection rate of six percent among partners of men who have sex with men (MSM) who were not diagnosed with HIV (Stekler et al., *Clin Infect Dis 2003;* 40:787-793). In particular, in populations where HIV prevalence is relatively high (e.g., sexually transmitted infection (STI)-infected attendees of some STD clinics), the potential to miss HIV co-infection may warrant increased efforts to have the patient/partner seen by a clinician.

Decisions about the appropriateness of FDT should be made on the basis of local epidemiology.

Appendix B.

SUGGESTED TEMPLATE FOR POLICIES AND PROCEDURES

Health department staff will:

- pre-arrange a time/place to meet the patient or partner;
- confirm identity of the patient or partner;
- assess treatment status to determine whether treatment for the infection has been received by the patient/partner;
- educate the patient/partner about STD risk, condoms, the diagnosed disease, and possible co-infections;
- determine whether the patient/partner is unable or unlikely to attend a health department clinic or an appointment with another clinician. Every effort should be made to refer the patient/partner to his/her healthcare provider or a health department clinician for treatment.

If the patient/partner is unable or unlikely to see a clinician, health department staff should proceed to:

- assess contraindications;
- educate patient/partner about:
  - medication, potential reactions, and how to seek help; and
  - abstinence during the period of drug action;
- obtain informed consent from the patient/partner;
- deliver medication or prescription from Health Officer or STD Controller;
- if medication is delivered and observed, monitor the patient for adverse reactions;
  - It is recommended that a clinician be on call to accept patients with adverse reactions.
- recommend re-testing in three months;
- document encounter, including lot number and expiration date of the medication administered.

Health department staff will educate patient/partner about the necessity to inform partners and bring them for treatment. Staff may provide partner packs for PDPT if it is assessed that the partner(s) is/are unlikely to seek timely treatment.

Appendix C.

PATIENT MATERIALS

I. Patient education materials

Patient education materials should include written information about the patient's infection and treatment, as well as counseling regarding partner evaluation and treatment, safer sex and risk reduction, and the importance of follow-up at a medical clinic.

These materials should also include information about adverse reactions to treatment and contact information in case of adverse reaction or general questions.

Sample educational materials will be made available upon request by the California Department of Public Health, STD Control Branch.

Appendix C , cont'd.

II. Sample patient consent form

Field-Delivered Treatment Record

Client name_____ DOB __/__/____Test result date __/__/____
Client gender: F M FTM MTF Diagnosis: CT GC Contact to CT Contact to GC
Testing site_____
Medication ordered by _____ Date ordered__/__/____
Lot number(s) _____ Expiration date__/__/____
Medication ordered by _____ Date ordered__/__/____
Lot number_____ Expiration date__/__/____
Treatment delivered by _____ Date__/__/____ DOT: Y N

Explain the following items to client and check to indicate completion:

- Clinical importance of chlamydia and gonorrhea infections, including symptoms and complications; supply patient with written materials.
- Risk reduction and safer sex
- Indicate clinic referral here: _____.
  If patient is unable/unwilling to attend clinic, proceed with checklist.
- Does the client currently have any of the following symptoms?

  Females:
  - Lower abdominal pain
  - Pain with sex
  - Fever
  - Indication of severe allergy (e.g., anaphylaxis, Stevens Johnson syndrome, toxic epidermal necrolysis):
    - penicillin and/or cephalosporins, including cefixime for patients in need of treatment for GC
    - macrolides, including azithromycin, for patients in need of treatment for CT or GC

  (allergy risk and other drug information is detailed in Appendix E)
  - Serious illness such as heart, liver, or kidney disease
  - If pregnant, the case should be reviewed by a health department physician.

Appendix C , cont'd.

Males:

- Pain or swelling in testicles
- Fever
- Indication of severe allergy (e.g., anaphylaxis, Stevens Johnson syndrome, toxic epidermal necrolysis):
  - penicillin and/or cephalosporins, including cefixime for patients in need of treatment for GC
  - macrolides, including azithromycin, for patients in need of treatment for CT or GC

(allergy risk and other drug information is detailed in Appendix E)

- Serious illness such as heart, liver, or kidney disease

If yes, DO NOT TREAT. Refer to clinic.

- Review written materials about treatment, including abstinence for seven days.
- Provide treatment (indicate as appropriate).

I give my consent to receive treatment for chlamydia/gonorrhea. The information provided about my current health status is correct to the best of my knowledge.

_____ _____

Patient signature Date Field staff signature Date

Appendix D.

NATIONAL GUIDANCE

The Centers for Disease Control and Prevention's 2008 report entitled "Recommendations for Partner Services Programs for HIV Infection, Syphilis, Gonorrhea and Chlamydial Infection" (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5709a1.htm) supports FDT for gonorrhea and chlamydia. The summary recommendations specifically state: "Programs should consider FDT for gonorrhea and chlamydial infection when partners are notified via provider referral" (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5709a2.htm).

The Centers for Disease Control and Prevention (CDC) Sexually Transmitted Disease (STD) Prevention Program has released a Dear Colleague letter: (http://www.cdc.gov/std/DearColleagueEPT5-10-05.pdf) and a white paper: (http://www.cdc.gov/std/treatment/EPTFinalReport2006.pdf), discussing the use of expedited partner therapy (EPT), or delivering medication to the partner of a case-patient via the case-patient, without a visit to a doctor by the partner.

While the EPT documents do not address field-delivered treatment (FDT) specifically, the practice is analogous to FDT for partners or for case-patients seen by non-health department clinicians in that there is no clinical evaluation by the provider administering the medication. CDC has endorsed the safety of EPT; FDT by a trained health department staff person is likely to be as safe as or safer than this CDC-endorsed practice.

Appendix E.

ALLERGY RISK AND OTHER DRUG INFORMATION

One study found a rate of immunoglobulin E (IgE)-associated cross-reactivity between penicillin and cephalosporins of ten percent (previously, best estimates suggested three percent to seven percent); however, IgE-associated reactivity does not invariably lead to symptoms of allergy. The incidence of allergic reactions to cephalosporins has been calculated to be one percent to three percent, with more penicillin cross-reactivity occurring with first-generation than with second- or third-generation cephalosporins such as cefixime (Pichichero M, *Pediatrics* 2005; 115:1048-1057).

A very large study found that, although patients who had allergic-like events after taking penicillin were more likely to have allergic-like events after a subsequent prescription of cefpodoxime than were those who did not have a reaction to the initial penicillin, patients were as likely to have allergic-like events if the subsequent prescription was a sulfonamide as they were if it were cefpodoxime. This study found an absolute risk of anaphylaxis after cephalosporin treatment of less than 0.001 percent (Apter AJ et al., *Am J Med* 2006; 119:354.e11-354.e20). Therefore, the risk of anaphylaxis due to FDT with cefpodoxime is low.

Patients with history of severe allergy (e.g., anaphylaxis, Stevens Johnson syndrome, toxic epidermal necrolysis) to any antibiotic should be assessed in the clinic setting rather than offered FDT.

Current information indicates that "allergy" due to azithromycin is rare to nonexistent.

Appendix F.

QUESTIONS AND ANSWERS

Are the medications safe? The medications recommended for FDT for CT (azithromycin) or GC (cefixime plus azithromycin) are safe and have few side effects. FDT of persons diagnosed with CT/GC, or of the partners of persons diagnosed with CT/GC, is analogous to PDPT, with the additional safety that FDT is delivered by trained health department personnel, including registered nurses, public health nurses, disease investigators, or public health investigators. FDT is a low-risk procedure and is an option for high-risk, uninsured patients or partners with no access to timely health care.

Should health department staff be purchasing and distributing medications? Untreated cases of CT or GC are a public health concern. Therefore, it is appropriate for treatment of these cases to be delivered by health department personnel, and appropriate for the medication delivered by health departments to be purchased under public health pricing.

What about the possibility of overuse or misuse of antibiotics? Because FDT is recorded at the clinic and is delivered by trained health department personnel, the risk for overuse or misuse of antibiotics is minimal and less than that for partner-delivered treatment.

Appendix G.

BIBLIOGRAPHY

Few published studies address field-delivered treatment directly. Studies and editorials addressing this topic are listed here:

1. Auerswald CL, Sugano E, Ellen JM, Klausner JD. Street-based STD testing and treatment of homeless youth are feasible, acceptable, and effective. *J Adolesc Health* 2006; 38(3):208-212.
2. Golden MR. Expedited partner therapy for sexually transmitted diseases. *Clin Infect Dis* 2005; 41(5):630-633.
3. Steiner KC, Davila V, Kent CK, et al. FDT increases treatment for chlamydia and GC. *Am J Public Health* 2003; 93(6):882-884.

Studies addressing the risk of co-infection:

1. Khan A, Fortenberry JD, Juliar BE, et al. The prevalence of chlamydia, GC, and trichomonas in sexual partnerships: implications for partner notification and treatment. *Sex Transm Dis* 2005; 32(4):260-264.
2. Stekler J, Bachmann L, Brotman RM, et al. Concurrent sexually transmitted infections (STIs) in sex partners of patients with selected STIs: implications for patient-delivered partner therapy. *Clin Infect Dis* 2005; 40(6):787-93.

Studies addressing allergy risk:

1. Pichichero M. A review of evidence supporting the American Academy of Pediatrics Recommendation for prescribing cephalosporin antibiotics for penicillin-allergic patients. *Pediatrics* 2005; 115:1048-1057.
2. Apter AJ, Kinman JL, Bilker WB, et al. Is there cross-reactivity between penicillins and cephalosporins? *Am J Med* 2006; 119:354.e11-354.e20.
3. Yates AB. Management of patients with a history of allergy to betalactam antibiotics. Am J Jed 2008:121:572-6.

Guidelines for Patient-Delivered Partner Therapy:

1. California Department of Public Health , STD Control Branch. Patient-Delivered Partner Therapy for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*: Guidance for Medical Providers in California" is available online: http://www.cdph.ca.gov/pubsforms/Guidelines/Documents/PDPT-Guidelines-and-Ptnr-Info-Engl-Span.pdf
2. The CDC maintains an EPT-focused website: (http://www.cdc.gov/std/ept/default.htm) with links to EPT guidelines and other relevant resources.