



# **Complete Summary**

#### **GUIDELINE TITLE**

Proctitis, proctocolitis, and enteritis. Sexually transmitted diseases treatment guidelines 2006.

## **BIBLIOGRAPHIC SOURCE(S)**

Centers for Disease Control and Prevention, Workowski KA, Berman SM. Proctitis, proctocolitis, and enteritis. Sexually transmitted diseases treatment guidelines 2006. MMWR Morb Mortal Wkly Rep 2006 Aug 4;55(RR-11):78. [222 references]

## **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previous version: Centers for Disease Control and Prevention. Proctitis, proctocolitis, and enteritis. Sexually transmitted diseases treatment guidelines. MMWR Recomm Rep 2002 May 10;51(RR-6):66-7.

## **\*\* REGULATORY ALERT \*\***

## FDA WARNING/REGULATORY ALERT

**Note from the National Guideline Clearinghouse**: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

• <u>September 11, 2007, Rocephin (ceftriaxone sodium)</u>: Roche informed healthcare professionals about revisions made to the prescribing information for Rocephin to clarify the potential risk associated with concomitant use of Rocephin with calcium or calcium-containing solutions or products.

## COMPLETE SUMMARY CONTENT

\*\* REGULATORY ALERT \*\* SCOPE METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS EVIDENCE SUPPORTING THE RECOMMENDATIONS BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS IMPLEMENTATION OF THE GUIDELINE INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

# IDENTIFYING INFORMATION AND AVAILABILITY DISCLAIMER

## SCOPE

## DISEASE/CONDITION(S)

Sexually transmitted gastrointestinal syndromes, including proctitis, proctocolitis, and enteritis

## **GUIDELINE CATEGORY**

Diagnosis Evaluation Management Treatment

## **CLINICAL SPECIALTY**

Family Practice Gastroenterology Infectious Diseases Internal Medicine Obstetrics and Gynecology Preventive Medicine

## **INTENDED USERS**

Health Care Providers Managed Care Organizations Physicians

## **GUIDELINE OBJECTIVE(S)**

- To update the Sexually Transmitted Diseases Treatment Guidelines 2002 (*MMWR 2002;51[No. RR-6]*)
- To assist physicians and other health-care providers in preventing and treating sexually transmitted diseases (STDs)

## TARGET POPULATION

Patients with suspected or documented acute sexually transmitted proctitis, proctocolitis, and enteritis

## INTERVENTIONS AND PRACTICES CONSIDERED

#### Diagnosis

1. Evaluation of signs and symptoms (e.g., diarrhea, abdominal cramps, inflammation of the colonic mucosa, pain, tenesmus, rectal discharge)

- 2. Anoscopy
- 3. Sigmoidoscopy
- 4. Stool examination
- 5. Presence of polymorphonuclear leukocytes on Gram-stained anorectal secretion smears
- 6. Stool culture

## Treatment/Management

- 1. Ceftriaxone (or another agent effective against rectal and genital gonorrhea) plus doxycycline
- 2. Follow-up care
- 3. Management of sex partners

# MAJOR OUTCOMES CONSIDERED

- Microbiologic cure
- Alleviation of signs and symptoms
- Prevention of sequelae
- Prevention of transmission

# METHODOLOGY

## METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

# DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

## NUMBER OF SOURCE DOCUMENTS

Not stated

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Subjective Review

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

## METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Beginning in 2004, the Centers for Disease Control and Prevention (CDC) personnel and professionals knowledgeable in the field of sexually transmitted diseases (STDs) systematically reviewed evidence (including published abstracts and peer-reviewed journal articles) concerning each of the major STDs, focusing on information that had become available since publication of the *Sexually Transmitted Diseases Treatment Guidelines, 2002*. Background papers were written and tables of evidence constructed summarizing the type of study (e.g., randomized controlled trial or case series), study population and setting, treatments or other interventions, outcome measures assessed, reported findings, and weaknesses and biases in study design and analysis. A draft document was developed on the basis of the reviews.

# METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Consensus Development Conference)

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

In April 2005, the Centers for Disease Control and Prevention (CDC) staff members and invited consultants assembled in Atlanta, Georgia, for a 3-day meeting to present the key questions regarding sexually transmitted disease (STD) treatment that emerged from the evidence-based reviews and the information available to answer those questions. When relevant, the questions focused on four principal outcomes of STD therapy for each individual disease: 1) microbiologic cure, 2) alleviation of signs and symptoms, 3) prevention of sequelae, and 4) prevention of transmission. Cost-effectiveness and other advantages (e.g., single-dose formulations and directly observed therapy of specific regimens) also were discussed. The consultants then assessed whether the questions identified were relevant, ranked them in order of priority, and attempted to arrive at answers using the available evidence. In addition, the consultants evaluated the quality of evidence supporting the answers on the basis of the number, type, and quality of the studies.

# **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS**

Not applicable

## COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

## METHOD OF GUIDELINE VALIDATION

Peer Review

#### **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

Not stated

## RECOMMENDATIONS

#### MAJOR RECOMMENDATIONS

Sexually transmitted gastrointestinal syndromes include proctitis, proctocolitis, and enteritis. Evaluation for these syndromes should include appropriate diagnostic procedures (e.g., anoscopy or sigmoidoscopy, stool examination, and culture).

Proctitis is inflammation of the rectum (i.e., the distal 10-12 cm) that might be associated with anorectal pain, tenesmus, or rectal discharge. *Neisseria gonorrhoeae*, *Chlamydia trachomatis* (including lymphogranuloma venereum [LGV] serovars), *Treponema pallidum*, and herpes simplex virus (HSV) are the most common sexually transmitted pathogens involved. In patients coinfected with human immunodeficiency virus (HIV), herpes proctitis might be especially severe. Proctitis occurs predominantly among persons who participate in receptive anal intercourse.

Proctocolitis is associated with symptoms of proctitis and diarrhea or abdominal cramps and inflammation of the colonic mucosa, extending to 12 cm above the anus. Fecal leukocytes might be detected on stool examination, depending on the pathogen. Pathogenic organisms include *Campylobacter sp.*, *Shigella sp.*, *Entamoeba histolytica*, and rarely, LGV serovars of *C. trachomatis*. Cytomegalovirus (CMV) or other opportunistic agents might be involved in immunosuppressed HIV-infected patients. Proctocolitis can be acquired by the oral route or by oral-anal contact, depending on the pathogen.

Enteritis usually results in diarrhea and abdominal cramping without signs of proctitis or proctocolitis; it occurs among persons whose sexual practices include oral-anal contact. In otherwise healthy persons, *Giardia lamblia* is most frequently implicated. When outbreaks of gastrointestinal illness occur among social or sexual networks of men who have sex with men (MSM), clinicians should consider sexual transmission as a mode of spread and provide counseling accordingly. Among HIV-infected patients, gastrointestinal illness can be caused by other infections that usually are not sexually transmitted, including CMV, *Mycobacterium avium-intracellulare, Salmonella sp., Campylobacter sp., Shigella sp., Cryptosporidium, Microsporidium,* and *Isospora*. Multiple stool examinations might be necessary to detect *Giardia*, and special stool preparations are required to diagnose cryptosporidiosis and microsporidiosis. In addition, enteritis might be directly caused by HIV infection.

When laboratory diagnostic capabilities are available, treatment decisions should be based on the specific diagnosis. Diagnostic and treatment recommendations for all enteric infections are beyond the scope of these guidelines.

## Treatment

Acute proctitis of recent onset among persons who have recently practiced receptive anal intercourse is usually sexually acquired. Such patients should be examined by anoscopy and should be evaluated for infection with HSV, *N. gonorrhoeae*, *C. trachomatis*, and *T. pallidum*. If an anorectal exudate is detected

on examination or if polymorphonuclear leukocytes are detected on a Gramstained smear of anorectal secretions, the following therapy may be prescribed while awaiting additional laboratory tests.

## Recommended Regimen

• **Ceftriaxone** 125 mg intramuscularly (IM) (or another agent effective against rectal and genital gonorrhea)

## PLUS

• **Doxycycline** 100 mg orally twice a day for 7 days

Patients with suspected or documented herpes proctitis should be managed in the same manner as those with genital herpes (see the National Guideline Clearinghouse summary of the Centers for Disease Control and Prevention guideline <u>Diseases Characterized by Genital Ulcers</u>, the section Genital HSV Infections). If painful perianal ulcers are present or mucosal ulcers are detected on anoscopy, presumptive therapy should include a regimen for treating genital herpes. In addition, LGV proctitis and proctocolitis also should be considered. Appropriate diagnostic testing for LGV should be conducted in accordance with state or federal guidelines, and doxycycline therapy should be administered 100 mg orally twice daily for 3 weeks.

## Follow-Up

Follow-up should be based on specific etiology and severity of clinical symptoms. Reinfection might be difficult to distinguish from treatment failure.

## **Management of Sex Partners**

Partners of patients with sexually transmitted enteric infections should be evaluated for any diseases diagnosed in the index patient.

## CLINICAL ALGORITHM(S)

None provided

# **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

## TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

Throughout the 2006 guideline document, the evidence used as the basis for specific recommendations is discussed briefly. More comprehensive, annotated discussions of such evidence will appear in background papers that will be published in a supplement issue of the journal *Clinical Infectious Diseases*.

## **BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS**

#### **POTENTIAL BENEFITS**

Appropriate diagnosis, management and treatment of patients who have acute proctitis, proctocolitis, and enteritis

#### **POTENTIAL HARMS**

Not stated

## QUALIFYING STATEMENTS

#### **QUALIFYING STATEMENTS**

- These recommendations were developed in consultation with public- and private-sector professionals knowledgeable in the treatment of patients with sexually transmitted diseases (STDs). The recommendations are applicable to various patient-care settings, including family planning clinics, private physicians' offices, managed care organizations, and other primary-care facilities.
- These recommendations are meant to serve as a source of clinical guidance: health-care providers should always consider the individual clinical circumstances of each person in the context of local disease prevalence. These guidelines focus on the treatment and counseling of individual patients and do not address other community services and interventions that are important in STD/human immunodeficiency virus (HIV) prevention.
- Diagnostic and treatment recommendations for all enteric infections are beyond the scope of these guidelines.

## **IMPLEMENTATION OF THE GUIDELINE**

#### **DESCRIPTION OF IMPLEMENTATION STRATEGY**

An implementation strategy was not provided.

#### **IMPLEMENTATION TOOLS**

Personal Digital Assistant (PDA) Downloads

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

#### IOM CARE NEED

Getting Better Staying Healthy

## **IOM DOMAIN**

Effectiveness

#### IDENTIFYING INFORMATION AND AVAILABILITY

#### **BIBLIOGRAPHIC SOURCE(S)**

Centers for Disease Control and Prevention, Workowski KA, Berman SM. Proctitis, proctocolitis, and enteritis. Sexually transmitted diseases treatment guidelines 2006. MMWR Morb Mortal Wkly Rep 2006 Aug 4;55(RR-11):78. [222 references]

#### ADAPTATION

Not applicable: The guideline was not adapted from another source.

#### DATE RELEASED

1993 (revised 2006 Aug 4)

## **GUIDELINE DEVELOPER(S)**

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

#### **GUIDELINE DEVELOPER COMMENT**

These guidelines for the treatment of persons who have sexually transmitted diseases (STDs) were developed by CDC after consultation with a group of professionals knowledgeable in the field of STDs who met in Atlanta, Georgia, during April 19–21, 2005.

## SOURCE(S) OF FUNDING

United States Government

#### **GUIDELINE COMMITTEE**

Not stated

#### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

## **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previous version: Centers for Disease Control and Prevention. Proctitis, proctocolitis, and enteritis. Sexually transmitted diseases treatment guidelines. MMWR Recomm Rep 2002 May 10;51(RR-6):66-7.

#### GUIDELINE AVAILABILITY

Electronic copies: Available from the Centers for Disease Control and Prevention (CDC) Web site:

- HTML Format
- Portable Document Format (PDF)

Print copies: Available from the Centers for Disease Control and Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

## AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Workowski KA, Levine WC, Wasserheit JN. U.S. Centers for Disease Control and Prevention guidelines for the treatment of sexually transmitted diseases: an opportunity to unify clinical and public health practice. Ann Intern Med. 2002 Aug 20;137(4):255-62. Electronic copies: Available through <u>Annals of</u> <u>Internal Medicine Online</u>.
- The CDC Sexually Transmitted Diseases Treatment Guidelines 2004 for PDA or Palm OS. Available from the <u>CDC National Prevention Information Network</u> (<u>NPIN) Web site</u>.

## **PATIENT RESOURCES**

None available

#### NGC STATUS

This summary was completed by ECRI on September 5, 2002. This NGC summary was updated by ECRI on October 18, 2006. This summary was updated by ECRI

Institute on October 3, 2007 following the U.S. Food and Drug Administration (FDA) advisory on Rocephin (ceftriaxone sodium).

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