Complete Summary

GUIDELINE TITLE

Congenital syphilis. Sexually transmitted diseases treatment guidelines 2002.

BIBLIOGRAPHIC SOURCE(S)

Centers for Disease Control and Prevention. Congenital syphilis. Sexually transmitted diseases treatment guidelines. MMWR Recomm Rep 2002 May 10;51(RR-6):26-8.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Congenital syphilis

GUIDELINE CATEGORY

Evaluation
Management
Prevention
Screening
Treatment

CLINICAL SPECIALTY

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

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Managed Care Organizations
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To update the 1998 Guidelines for Treatment of Sexually Transmitted Diseases (MMWR 1998;47[No. RR-1])
- To assist physicians and other health-care providers in preventing and treating sexually transmitted diseases (STDs)
- To present updated recommendations for the diagnosis, treatment, and prevention of congenital syphilis

TARGET POPULATION

- Infants born to mothers who have reactive serologic tests for syphilis
- Children who are identified as having reactive serologic tests for syphilis after the neonatal period
- Pregnant women

INTERVENTIONS AND PRACTICES CONSIDERED

Note from the National Guideline Clearinghouse and the Centers for Disease Control and Prevention: These guidelines focus on the treatment and counseling of individual patients and do not address other community services and interventions that are important in sexually transmitted disease/human immunodeficiency virus (STD/HIV) prevention.

Diagnosis/Evaluation

1. Serologic screening of pregnant women for syphilis at the time of first prenatal visit.
2. Serologic testing and sexual history of pregnant women at 28 weeks gestation and at delivery in communities and populations in which the risk for congenital syphilis is high
3. HIV testing in pregnant women with syphilis
4. Examination of all infants born to women who have reactive serologic tests of syphilis for evidence of congenital syphilis (e.g., nonimmune hydrops, jaundice, hepatosplenomegaly, rhinitis, skin rash, and/or pseudoparalysis of an extremity)
5. Pathological examination of the placenta or umbilical cord using fluorescent antitreponemal antibody staining
6. Quantitative nontreponemal serologic test on infant serum (rapid plasma reagin [RPR] or Venereal Disease Research Laboratory [VDRL] test)

7. Darkfield microscopic examination or direct fluorescent antibody staining of suspicious lesions or body fluids
8. Cerebrospinal fluid (CSF) analysis for Venereal Disease Research Laboratory test, cell count, and protein
9. Complete blood count (CBC), differential complete blood count, and platelet count
10. Other tests as clinically indicated (long-bone radiographs, chest radiographs, liver function tests, cranial ultrasound, ophthalmologic examination, auditory brainstem response)
11. Maternal serology and records review for children with reactive serologic tests after the neonatal period
12. HIV testing for any child at risk for congenital syphilis
13. Follow-up examinations and serologic testing

Note: Routine screening of newborn sera or umbilical cord blood was considered but not recommended.

Note: Treponemal tests (microhemagglutination assay for antibody treponemal antibody absorbed) of newborn sera were considered bit not recommended.

Treatment

1. Aqueous crystalline penicillin G
2. Procaine penicillin G
3. Benzathine penicillin G
4. Desensitization to penicillin

Note: Ampicillin and ceftriaxone are considered but not recommended.

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 2000, Centers for Disease Control and Prevention (CDC) personnel and professionals knowledgeable in the field of sexually transmitted diseases (STDs) systematically reviewed literature (i.e., published abstracts and peer-reviewed journal articles) concerning each of the major STDs, focusing on information that had become available since publication of the 1998 Guidelines for Treatment of Sexually Transmitted Diseases. 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

Not stated

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

Note from the National Guideline Clearinghouse (NGC) and the Centers for Disease Control and Prevention (CDC): When more than one therapeutic regimen is recommended, the sequence is alphabetized unless the choices for therapy are prioritized based on efficacy, convenience, or cost. For sexually transmitted diseases (STDs) with more than one recommended regimen, almost all regimens have similar efficacy and similar rates of intolerance or toxicity unless otherwise specified.

Effective prevention and detection of congenital syphilis depends on the identification of syphilis in pregnant women and, therefore, on the routine serologic screening of pregnant women during the first prenatal visit. Serologic testing and a sexual history also should be obtained at 28 weeks of gestation and at delivery in communities and populations in which the risk for congenital syphilis is high. Moreover, as part of the management of pregnant women who have syphilis, information concerning treatment of sex partners should be obtained to assess the risk for reinfection. All pregnant women who have syphilis should be tested for human immunodeficiency virus (HIV) infection.

Routine screening of newborn sera or umbilical cord blood is not recommended. Serologic testing of the mother's serum is preferred over testing infant serum, because the serologic tests performed on infant serum can be nonreactive if the mother's serologic test result is of low titer or if the mother was infected late in pregnancy. No infant or mother should leave the hospital unless the maternal serologic status has been documented at least once during pregnancy and preferably again at delivery.

Evaluation and Treatment of Infants in the First Month of Life

The diagnosis of congenital syphilis is complicated by the transplacental transfer of maternal nontreponemal and treponemal immunoglobulin G (IgG) antibodies to the fetus. This transfer of antibodies makes the interpretation of reactive serologic tests for syphilis in infants difficult. Treatment decisions often must be made on the basis of a) identification of syphilis in the mother; b) adequacy of maternal treatment; c) presence of clinical, laboratory, or radiographic evidence of syphilis in the infant; and d) comparison of maternal (at delivery) and infant nontreponemal serologic titers utilizing the same test and preferably the same laboratory.

All infants born to mothers who have reactive nontreponemal and treponemal test results should be evaluated with a quantitative nontreponemal serologic test (rapid plasma reagin [RPR] or Venereal Disease Research Laboratory [VDRL]) performed on infant serum, because umbilical cord blood can become contaminated with maternal blood and could yield a false-positive result. Conducting a treponemal test (i.e., treponemal pallidum particle agglutation [TP-PA]or fluorescent treponemal antibody absorbed [FTA-ABS]) on a newborn's serum is not necessary. Currently, no commercially available immunoglobulin M (IgM) test can be recommended.

All infants born to women who have reactive serologic tests for syphilis should be examined thoroughly for evidence of congenital syphilis (e.g., nonimmune hydrops, jaundice, hepatosplenomegaly, rhinitis, skin rash, and/or pseudoparalysis of an extremity). Pathologic examination of the placenta or umbilical cord using specific fluorescent antitreponemal antibody staining is suggested. Darkfield microscopic examination or direct fluorescent antibody staining of suspicious lesions or body fluids (e.g., nasal discharge) also should be performed.

The following scenarios describe the evaluation and treatment of infants for congenital syphilis.

Scenario 1. Infants with proven or highly probable disease

a. an abnormal physical examination that is consistent with congenital syphilis
b. a serum quantitative nontreponemal serologic titer that is fourfold greater than the mother's titer;*
c. a positive darkfield or fluorescent antibody test of body fluid(s)

*The absence of a fourfold or greater titer for an infant does not exclude congenital syphilis.

Recommended Evaluation

- Cerebrospinal fluid (CSF) analysis for VDRL, cell count, and protein.**
- Complete blood count (CBC) and differential and platelet count.
- Other tests as clinically indicated (e.g., long-bone radiographs, chest radiograph, liver-function tests, cranial ultrasound, ophthalmologic examination, and auditory brainstem response).

**CSF test results obtained during the neonatal period can be difficult to interpret; normal values differ by gestational age and are higher in preterm infants. Values as high as 25 white blood cells (WBCs)/mm^3 and/or protein of 150 mg/dL might occur among normal neonates; some specialists, however, recommend that lower values (i.e., 5 white blood cells/ mm^3 and protein of 40 mg/dL) be considered the upper limit of normal. Other causes of elevated values also should be considered when an infant is being evaluated for congenital syphilis.

Recommended Regimens

Aqueous crystalline penicillin G 100,000--150,000 units/kg/day, administered as 50,000 units/kg/dose intravenously every 12 hours during the first 7 days of life and every 8 hours thereafter for a total of 10 days

OR

Procaine penicillin G 50,000 units/kg/dose intramuscularly in a single daily dose for 10 days.

If more than 1 day of therapy is missed, the entire course should be restarted. Data are insufficient regarding the use of other antimicrobial agents (e.g., ampicillin). When possible, a full 10-day course of penicillin is preferred, even if ampicillin was initially provided for possible sepsis. The use of agents other than penicillin requires close serologic follow-up to assess adequacy of therapy. In all other situations, the maternal history of infection with T. pallidum and treatment for syphilis must be considered when evaluating and treating the infant.

Scenario 2. Infants who have a normal physical examination and a serum quantitative nontreponemal serologic titer the same or less than fourfold the maternal titer and the

a. mother was not treated, inadequately treated, or has no documentation of having received treatment;
b. mother was treated with erythromycin or other nonpenicillin regimen (Note: A woman treated with a regimen other than those recommended in the guidelines for treatment should be considered untreated);
c. mother received treatment $\leq$4 weeks before delivery; or
d. mother has early syphilis and has a nontreponemal titer that has either not decreased fourfold or has increased fourfold.

Recommended Evaluation

- CSF analysis for VDRL, cell count, and protein
- CBC and differential and platelet count
- Long-bone radiographs

A complete evaluation is not necessary if 10 days of parenteral therapy is administered. However, such evaluation may be useful; a lumbar puncture may document CSF abnormalities that would prompt close follow-up. Other tests (e.g., CBC, platelet count, and bone radiographs) may be performed to further support a diagnosis of congenital syphilis. If a single dose of benzathine penicillin G is used, then the infant must be fully evaluated (i.e., through CSF examination, long-bone radiographs, and CBC with platelets), the full evaluation must be normal, and follow-up must be certain. If any part of the infant's evaluation is abnormal or not performed, or if the CSF fluid analysis is rendered uninterpretable because of contamination with blood, then a 10-day course of penicillin is required. (Note: If the infant's nontreponemal test is nonreactive and the likelihood of the infant being infected is low, Some specialists recommend no evaluation but treatment of the infant with a single intramuscular dose of benzathine penicillin G 50,000 units/kg for possible incubating syphilis, after which the infant should receive close serologic follow-up.)

Recommended Regimens

Aqueous crystalline penicillin G 100,000--150,000 units/kg/day, administered as 50,000 units/kg/dose intravenously every 12 hours during the first 7 days of life and every 8 hours thereafter for a total of 10 days

OR

Procaine penicillin G 50,000 units/kg/dose intramuscularly in a single daily dose for 10 days

OR

Benzathine penicillin G 50,000 units/kg/dose intramuscularly in a single dose

NOTE: Some specialists prefer the 10 days of parenteral therapy if the mother has untreated early syphilis at delivery.

Scenario 3. Infants who have a normal physical examination and a serum quantitative nontreponemal serologic titer the same or less than fourfold the maternal titer and the

a. mother was treated during pregnancy, treatment was appropriate for the stage of infection, and treatment was administered >4 weeks before delivery;
b. mother's nontreponemal titers decreased fourfold after appropriate therapy for early syphilis or remained stable and low for late syphilis; and
c. mother has no evidence of reinfection or relapse.

Recommended Evaluation

No evaluation is required.

Recommended Regimen

Benzathine penicillin G 50,000 units/kg/dose intramuscularly in single dose. (Note: Some specialists would not treat the infant but would provide close serologic follow-up.)

Scenario 4. Infants who have a normal physical examination and a serum quantitative nontreponemal serologic titer the same or less than fourfold the maternal titer and the

a. mother's treatment was adequate before pregnancy and
b. mother's nontreponemal serologic titer remained low and stable before and during pregnancy and at delivery (VDRL $\leq$1:2; rapid plasma reagin $\leq$1:4).

Recommended Evaluation

No evaluation is required.

Recommended Regimen

No treatment is required; however, some specialists would treat with benzathine penicillin G 50,000 units/kg as a single intramuscular injection, particularly if follow-up is uncertain.

Evaluation and Treatment of Older Infants and Children

Children who are identified as having reactive serologic tests for syphilis after the neonatal period (i.e., at >1 month of age) should have maternal serology and records reviewed to assess whether the child has congenital or acquired syphilis (for acquired syphilis, see the National Guideline Clearinghouse [NGC] summary of the CDC guideline Diseases Characterized by Genital Ulcers, sections on Primary and Secondary Syphilis and Latent Syphilis. Any child at risk for congenital syphilis should receive a full evaluation and testing for human immunodeficiency virus (HIV) infection.

Recommended Evaluation

- CSF fluid analysis for VDRL, cell count, and protein.
- Complete blood count (CBC), differential, and platelet count.
- Other tests as clinically indicated (e.g., long-bone radiographs, chest radiograph, liver function tests, abdominal ultrasound, ophthalmologic examination, and auditory brain stem response).

Recommended Regimens

Aqueous crystalline penicillin G 200,000--300,000 units/kg/day intravenously, administered as 50,000 units/kg every 4--6 hours for 10 days.

Any child who is suspected of having congenital syphilis or who has neurologic involvement should be treated with aqueous penicillin G. Some specialists also suggest giving these patients a single dose of benzathine penicillin G, 50,000 units/kg intramuscularly following the 10-day course of intravenous aqueous penicillin.

Follow-Up

All seroreactive infants (or infants whose mothers were seroreactive at delivery) should receive careful follow-up examinations and serologic testing (i.e., a nontreponemal test) every 2--3 months until the test becomes nonreactive or the titer has decreased fourfold. Nontreponemal antibody titers should decline by 3 months of age and should be nonreactive by 6 months of age if the infant was not infected (i.e., if the reactive test result was caused by passive transfer of maternal immunoglobulin G antibody) or was infected but adequately treated. The serologic response after therapy may be slower for infants treated after the neonatal period. If these titers are stable or increase after 6--12 months of age, the child should be evaluated (e.g., given a CSF examination) and treated with a 10-day course of parenteral penicillin G.

Treponemal tests should not be used to evaluate treatment response because the results for an infected child can remain positive despite effective therapy. Passively transferred maternal treponemal antibodies can be present in an infant until age 15 months. A reactive treponemal test after age 18 months is diagnostic of congenital syphilis. If the nontreponemal test is nonreactive at this time, no further evaluation or treatment is necessary. If the nontreponemal test is reactive at age 18 months, the infant should be fully (re)evaluated and treated for congenital syphilis.

Infants whose initial CSF evaluations are abnormal should undergo a repeat lumbar puncture approximately every 6 months until the results are normal. A reactive CSF VDRL or abnormal CSF indices that cannot be attributed to other ongoing illness requires re-treatment for possible neurosyphilis.

Follow-up of children treated for congenital syphilis after the newborn period should be conducted as is recommended for neonates.

Special Considerations

Penicillin Allergy

Infants and children who require treatment for syphilis but who have a history of penicillin allergy or develop an allergic reaction presumed secondary to penicillin should be desensitized, if necessary, and then treated with penicillin (see the NGC summary of the CDC guideline Management of Patients With a History of Penicillin Allergy. Data are insufficient regarding the use of other antimicrobial agents (e.g., ceftriaxone); if a nonpenicillin agent is used, close serologic and CSF follow-up are indicated.

HIV Infection

Data are insufficient regarding whether infants who have congenital syphilis and whose mothers are coinfected with HIV require different evaluation, therapy, or follow-up for syphilis than is recommended for all infants.

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 2002 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

Effective prevention, detection, and treatment of congenital syphilis

POTENTIAL HARMS

Penicillin can cause allergic reactions in penicillin-allergic patients

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). They are applicable to various patient-care settings, including family planning clinics, private physicians' offices, managed care organizations, and other primary-care facilities. When using these guidelines, the disease prevalence and other characteristics of the medical practice setting should be considered. These recommendations should be regarded as a source of clinical guidance and not as standards or inflexible rules. These guidelines focus on the treatment and counseling of individual patients and do not address other community services and interventions that are important in sexually transmitted disease/human immunodeficiency virus (STD/HIV) prevention.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

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. Congenital syphilis. Sexually transmitted diseases treatment guidelines. MMWR Recomm Rep 2002 May 10;51(RR-6):26-8.

ADAPTATION

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

DATE RELEASED

1993 (revised 2002 May 10)

GUIDELINE DEVELOPER(S)

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

GUIDELINE DEVELOPER COMMENT

These guidelines for the treatment of patients who have sexually transmitted diseases (STDs) were developed by the Centers for Disease Control and Prevention (CDC) after consultation with a group of professionals knowledgeable in the field of STDs who met in Atlanta on September 26--28, 2000.

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

Not stated

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

The information in this report updates the "1998 Sexually Transmitted Diseases Treatment Guidelines" (MMWR 1998;47[No. RR-1]).

GUIDELINE AVAILABILITY

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

- HTML version
- 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 Annals of Internal Medicine Online.
- Sexually Transmitted Diseases Treatment Guidelines 2002 for PDA or Palm OS. Available from the CDC National Prevention Information Network (NPIN) Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on August 19, 2002.

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