Complete Summary

GUIDELINE TITLE

Hepatitis C. Sexually transmitted diseases treatment guidelines 2006.

BIBLIOGRAPHIC SOURCE(S)

Centers for Disease Control and Prevention, Workowski KA, Berman SM. Hepatitis C. Sexually transmitted diseases treatment guidelines 2006. MMWR Morb Mortal Wkly Rep 2006 Aug 4;55(RR-11):76-8. [222 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Centers for Disease Control and Prevention. Hepatitis C. Sexually transmitted diseases treatment guidelines. MMWR Recomm Rep 2002 May 10;51(RR-6):64-6.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Hepatitis C

GUIDELINE CATEGORY

Counseling
Diagnosis
Management
Prevention
Treatment

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Internal Medicine
Obstetrics and Gynecology
Pediatrics
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

Persons infected with hepatitis C and persons seeking care in a sexually transmitted disease (STD) clinic or other primary-care setting that also have the following risk factors:

- Illegal injection drug use
- Recipient of blood transfusion or solid organ transplant before July 1992
- Recipient of clotting factor concentrates produced before 1987
- Long-term dialysis
- Signs and symptoms of liver disease (e.g., abnormal alanine aminotransferase [ALT])

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. Detection of antibodies to hepatitis C virus (anti-HCV) using enzyme immunoassay (EIA) test
2. Detection of HCV ribonucleic acid (RNA) by reverse transcriptase polymerase chain reaction (RT-PCR)

Treatment/Management

1. Pegylated interferon with ribavirin for chronic liver disease

Primary Prevention (reduction or elimination of HCV transmission)

1. Counseling persons who use or inject illegal drugs to:

    - Stop using and injecting drugs
    - Enter and complete substance abuse treatment, including relapse prevention
    - Take steps to reduce personal and private health risks if continue to inject drugs
2. Postexposure follow-up

Secondary Prevention (reduction of sequelae in HCV -infected individuals)

1. Providing information on how patients can protect their livers from further harm (avoid alcohol, avoid taking new medicines, including over-the-counter and herbal agents, without checking with doctor
2. Considering vaccination against hepatitis A and B
3. Providing information on how patients can prevent transmission to others by advising
    - Not to donate blood, body organs, other tissue, or semen
    - Not to share any personal items that may have blood on them, such as toothbrushes or razors
    - To cover cuts and sores on the skin
4. Instructing patients about the importance of medical evaluation for chronic liver disease, including assessment of liver function tests, and possible treatment
5. Counseling HCV-positive persons with one long-term, steady sex partner to discuss the low but present risk for transmission with their partner and discuss the need for counseling and testing

Special Considerations

1. Counseling and testing for pregnant women with known risk factors for HCV infection
2. Testing of infants born to HCV-infected women and evaluation for chronic liver disease
3. Testing of patients with HIV

MAJOR OUTCOMES CONSIDERED

- Prevalence of hepatitis C virus infection
- Incidence and method of transmission
- Prevention of sequelae (e.g., chronic liver disease)
- Incidence of abnormal serum aminotransferase levels
- 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

Hepatitis C virus (HCV) infection is the most common chronic bloodborne infection in the United States; approximately 2.7 million persons are chronically infected. Although HCV is not efficiently transmitted sexually, persons at risk for infection through injection-drug use might seek care in sexually transmitted disease (STD) treatment facilities, human immunodeficiency virus (HIV) counseling and testing facilities, correctional facilities, drug treatment facilities, and other public health settings where STD and HIV prevention and control services are available.

Persons newly infected with HCV typically are either asymptomatic or have a mild clinical illness. HCV ribonucleic acid (RNA) can be detected in blood within 1-3 weeks after exposure. The average time from exposure to antibody to HCV (anti-HCV) seroconversion is 8-9 weeks, and anti-HCV can be detected in >97% of persons by 6 months after exposure. Chronic HCV infection develops in 60%-85% of HCV-infected persons; 60%-70% of chronically infected persons have evidence of active liver disease. The majority of infected persons might not be aware of their infection because they are not clinically ill. However, infected persons serve as a source of transmission to others and are at risk for chronic liver disease (CLD) or other HCV-related chronic diseases for decades after infection.

HCV is most efficiently transmitted through large or repeated percutaneous exposure to infected blood (e.g., through transfusion of blood from unscreened donors or through use of injecting drugs), although less efficient, occupational, perinatal, and sexual exposures also can result in transmission of HCV.

The role of sexual activity in the transmission of HCV has been controversial. Case-control studies have reported an association between acquiring HCV infection and exposure to a sex contact with HCV infection or exposure to multiple sex partners. Surveillance data also indicate that 15%-20% of persons reported with acute HCV infection have a history of sexual exposure in the absence of other risk factors. Case reports of acute HCV infection among HIV-positive men who have sex with men (MSM) who deny injecting-drug use have indicated that this occurrence is frequently associated with other STDs (e.g., syphilis). In contrast, a low prevalence (average: 1.5%) of HCV infection has been demonstrated in studies of long- term spouses of patients with chronic HCV infection who had no other risk factors for infection, and multiple published studies have demonstrated the prevalence of HCV infection among MSM who have not reported a history of injecting-drug use to be no higher than that of heterosexuals. Because sexual transmission of bloodborne viruses is more efficient among homosexual men compared with heterosexual men and women, the reason that HCV infection rates are not substantially higher among MSM compared with heterosexuals is unclear. Overall, these findings indicate that sexual transmission of HCV is possible but inefficient. Additional data are needed to determine whether sexual transmission of HCV might be increased in the context of HIV infection or other STDs.

Diagnosis and Treatment

Anti-HCV testing is recommended for routine screening of asymptomatic persons based on their risk for infection or based on a recognized exposure (see Prevention below). For such persons, testing for HCV infection should include the use of an FDA-cleared test for antibody to HCV (i.e., immunoassay, enzyme immunoassay [EIA], or enhanced chemiluminescence assay and, if recommended, a supplemental antibody test).

Persons counseled and tested for HCV infection and determined to be anti-HCV positive should be evaluated (by referral or consultation, if appropriate) for presence of active infection, presence or development of CLD, and for possible treatment. Reverse transcriptase polymerase chain reaction to detect HCV RNA may be used to confirm the diagnosis of current HCV infection, and an elevated alanine aminotransferase (ALT) level is biochemical evidence of CLD. Combination therapy with pegylated interferon and ribavirin is the treatment of choice for patients with chronic hepatitis C. Because of advances in the field of antiviral therapy for acute and chronic hepatitis C, clinicians should consult with specialists knowledgeable about management of hepatitis C infection.

Prevention

No vaccine for hepatitis C is available, and prophylaxis with immune globulin is not effective in preventing HCV infection after exposure. Reducing the burden of HCV infection and disease in the United States requires implementation of both primary and secondary prevention activities. Primary prevention reduces or eliminates HCV transmission; secondary prevention activities reduce liver and other chronic diseases in HCV-infected persons by identifying them and providing appropriate medical management and antiviral therapy, if appropriate.

Persons seeking care in STD clinics or other primary-care settings should be screened to identify those who should be offered HCV counseling and testing. In

STD clinics and other settings that serve large numbers of persons at high risk for bloodborne infections (e.g., correctional settings), the major risk factor for which to screen for HCV infection is injection of illegal drugs. In addition, for clinical management issues, all persons with HIV infection should also be offered HCV counseling and testing. Other risk factors for which routine HCV testing is recommended include persons

- who had a blood transfusion or solid organ transplant before July 1992
- who received clotting factor concentrates produced before 1987
- who have been on long-term dialysis
- those with signs and symptoms of liver disease (e.g., abnormal ALT)

Persons who test positive for anti-HCV (see Diagnosis and Treatment above) should be provided information regarding 1) how to protect their liver from further harm, 2) how to prevent transmission to others, and 3) the need for medical evaluation for CLD and possible treatment.

- To protect their liver from further harm, HCV-positive persons should be advised to avoid alcohol and taking any new medicines (including over-the-counter [OTC] and herbals) without checking with their doctor.
- To reduce the risk for transmission to others, HCV-positive persons should be advised to 1) not donate blood, body organs, other tissue, or semen; 2) not share any personal items that might have blood on them (e.g., toothbrushes and razors); and 3) cover cuts and sores on the skin to keep from spreading infectious blood or secretions. HCV-positive persons with one long-term, steady sex partner do not need to change their sexual practices. They should discuss the low but present risk for transmission with their partner and discuss the need for counseling and testing. HCV-positive women do not need to avoid pregnancy or breastfeeding.
- HCV-positive persons should be evaluated (by referral or consultation, if appropriate) for presence of development of CLD, including assessment of liver function tests, assessment for severity of liver disease and possible treatment, and determination of the need for hepatitis A and B vaccination.

Persons who test negative for anti-HCV who had an exposure previously should be reassured that they are not infected.

Regardless of test results, persons who use or inject illegal drugs should be counseled to

- stop using and injecting drugs
- enter and complete substance abuse treatment, including relapse prevention
- take the following steps to reduce personal and public health risks, if they continue to inject drugs:
    - never reuse or share syringes, water, or drug preparation equipment
    - use only syringes obtained from a reliable source (e.g., pharmacies
    - use a new, sterile syringe to prepare and inject drugs
    - if possible, use sterile water to prepare drugs; otherwise, use clean water from a reliable source (e.g., fresh tap water)
    - use a new or disinfected container ("cooker") and a new filter ("cotton") to prepare drugs
    - clean the injection site before injection with a new alcohol swab

- safely dispose of syringes after one use
- get vaccinated for hepatitis A and B

Postexposure Follow-Up

No postexposure prophylaxis (PEP) has been demonstrated to be effective against HCV. Testing to determine whether HCV infection has developed is recommended for health-care workers after percutaneous or permucosal exposures to HCV-positive blood and for children born to HCV-positive women.

Special Considerations

Pregnancy

Routine testing for HCV infection is not recommended for all pregnant women. Pregnant women with a known risk factor for HCV infection should be offered counseling and testing. Patients should be advised that approximately five of every 100 infants born to HCV-infected woman become infected. This infection occurs predominantly during or near delivery, and no treatment or delivery method is known to decrease this risk. The risk is increased by the presence of maternal HCV viremia at delivery and also is greater (2-3 times) if the woman is coinfected with HIV. Breastfeeding does not appear to transmit HCV, although HCV-positive mothers should consider abstaining from breastfeeding if their nipples are cracked or bleeding. Infants born to HCV-positive mothers should be tested for HCV infection and, if positive, evaluated for the presence of CLD.

HIV Infection

Because of the high prevalence of HIV/HCV coinfection and because of critical clinical management issues for coinfected persons, all HIV-infected persons should be tested for HCV. Because a small percentage of coinfected persons fail to acquire HCV antibodies, HCV RNA should be tested in HIV-positive persons with unexplained liver disease who are anti-HCV negative. The course of liver disease is more rapid in HIV/HCV coinfected persons, and the risk for cirrhosis is nearly twice that in persons with HCV infection alone. Treatment of HCV in coinfected persons might improve tolerance to highly active antiretroviral therapy (HAART) for HIV infection because of the increased risk for hepatotoxicity from HAART with HCV infection. However, anti-HCV treatment in coinfected persons is still investigational, and based on ongoing clinical trials, more data are needed to determine the best regimens.

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 and management of hepatitis C virus infection

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.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

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

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Centers for Disease Control and Prevention, Workowski KA, Berman SM. Hepatitis C. Sexually transmitted diseases treatment guidelines 2006. MMWR Morb Mortal Wkly Rep 2006 Aug 4;55(RR-11):76-8. [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. Hepatitis C. Sexually transmitted diseases treatment guidelines. MMWR Recomm Rep 2002 May 10;51(RR-6):64-6.

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 Annals of Internal Medicine Online.
- The CDC Sexually Transmitted Diseases Treatment Guidelines 2004 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 September 5, 2002. This summary was updated by ECRI on October 17, 2006.

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