# Complete Summary

## GUIDELINE TITLE

Management of hepatitis C: 2002.

## BIBLIOGRAPHIC SOURCE(S)

National Institutes of Health (NIH). Management of hepatitis C: 2002. Rockville (MD): National Institutes of Health (NIH); 2002 Aug 26. 44 p.

## COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
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## SCOPE

### DISEASE/CONDITION(S)

Hepatitis C

### GUIDELINE CATEGORY

Counseling
Diagnosis
Evaluation
Management
Prevention
Risk Assessment
Treatment

### CLINICAL SPECIALTY

Family Practice
Gastroenterology
Infectious Diseases
Internal Medicine
Oncology

Pathology
Pediatrics
Preventive Medicine

## INTENDED USERS

Physicians

## GUIDELINE OBJECTIVE(S)

- To update the 1997 Consensus Statement on the prevention, diagnosis, and treatment of hepatitis C virus (HCV) infection
- To address the following key questions:
    - What is the natural history of hepatitis C?
    - What is the most appropriate approach to diagnose and monitor patients?
    - What is the most effective therapy for hepatitis C?
    - Which patients with hepatitis C should be treated?
    - What recommendations can be made to patients to prevent transmission of hepatitis C?
    - What are the most important areas for future research?

## TARGET POPULATION

Patients with suspected or confirmed hepatitis C

## INTERVENTIONS AND PRACTICES CONSIDERED

### Diagnosis/Risk Assessment/Prognosis

1. History and physical examination
2. Testing
    - Hepatitis C virus (HCV) serologic assays: enzyme immunoassay (EIA) tests for anti-HCV detection and serological determination of HCV genotype
    - Qualitative HCV ribonucleic acid (RNA) assays
    - Quantitative HCV RNA assays (such as quantitative PCR [qPCR] or branched deoxyribonucleic acid [bDNA] signal amplification assay)
    - Serum alanine aminotransferase (ALT) levels
    - Noninvasive tests of hepatic fibrosis (e.g., liver-associated chemistries, platelet count, and prothrombin time, specific serum markers of fibrosis and inflammation)
    - Liver biopsy
    - Screening tests for hepatocellular carcinoma (HCC) (such as alpha-fetoprotein [AFP] and hepatic ultrasound)
    - Screening test for human immunodeficiency virus (HIV)

### Management/Treatment/Prevention/Counseling

1. Pharmacologic management (pegylated [peg] interferon plus ribavirin; peginterferon alone; standard interferon plus ribavirin; standard interferon plus amantadine; interferon monotherapy)
2. Retreatment of selected patients with pegylated interferon-based regimens
3. Measures to encourage adherence to HCV treatment (e.g. management of side effects, depression, and substance abuse)
4. Measures to prevent transmission of disease
    - Screening and testing of donor
    - Virus inactivation of plasma-derived precuts
    - Risk reduction counseling and services
    - Implementation and maintenance of infection-control practices
5. Measures to prevent chronic disease in patients with hepatitis C
    - Identification, counseling, and testing of at-risk persons
    - Medical evaluation and management of infected persons

### MAJOR OUTCOMES CONSIDERED

- Value of initial liver biopsy in predicting outcomes of treatment in patients with chronic hepatitis C virus (HCV) infection as measured by virologic and histologic measures of disease activity and progression
- Value of biochemical blood tests and serologic measures of fibrosis in predicting the findings of liver biopsy in patients with chronic HCV infection
- Sensitivity and specificity of diagnostic tests for HCV
- Sustained virological response (SVR), virologic response with relapse, and virologic non-response, as well as other clinical outcomes after treatment
- Safety and adverse effects of treatments
- Long-term clinical outcomes, including incidence of cirrhosis, hepatic decompensation, hepatocellular carcinoma, and death
- Value of using screening tests for hepatocellular carcinoma to improve clinical outcomes (mortality and rate of respectable verus nonresectable hepatocellular carcinoma) in patients with chronic HCV
- Sensitivity, specificity, and predictive values of tests to screen for hepatocellular carcinoma in patients with chronic HCV
- Morbidity, mortality, and health care costs related to HCV

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Under contract to the Agency for Healthcare Research and Quality (AHRQ), the Johns Hopkins University Evidence-based Practice Center collected the evidence. Several literature sources were used to identify all studies potentially relevant to the research questions. Eight electronic databases were searched through DIALOG (a commercial database vendor) for the period from January 1, 1996 to September 30, 2001: MEDLINE®; biological Abstracts-BIOSIS Previews®;

Science Citation Index-SciSearch®; Manual, Alternative and Natural Therapy™-MANTIS™; the Allied and Complementary Medicine Database; CAB Health; PsycINFO; and Sociological Abstracts. To ensure a comprehensive literature search and identification of all relevant articles, the Evidence Based Practice Center (EPC) team updated the search in March 2002, examined the reference lists from material identified through the electronic searching and discussion with experts, and reviewed the tables of contents of recent issues of journals that were cited most frequently (between October 2001 and March 2002).

Two members of the study team independently reviewed the titles and abstracts identified by the search to exclude those that did not meet the following eligibility criteria: 1) written in English; 2) includes human data; 3) original data; 4) information relevant to the management of hepatitis C; 5) reports basic sciences as well as clinical data; 6) applies to one of the key questions. Also excluded were meeting abstracts (no full article for review). Citations deemed not relevant by both reviewers were excluded. To focus the search on the studies that would be most valuable in addressing the key questions, the following types of studies were excluded: 1) studies in which all data was reported in a subsequent publication; 2) studies that may have contained some data related to a key question but the study was not designed to address the question; 3) studies that addressed management of hepatitis C in liver transplant patients only; 4) studies in which the total number of participants was less than 30; and 5) studies in which the outcomes/results were not measured with an appropriate objective standard (i.e., virologic and/or histologic measures of treatment response, or histologic or pathologic evidence of hepatocellular carcinoma [HCC] for the screening questions). The literature was searched through MEDLINE and an extensive bibliography of references was provided to the panel and the conference audience. Twenty-five experts prepared abstracts with relevant citations from the literature and presented data to the panel and a conference audience of 1,600. Questions and statements from conference attendees were considered during open discussion periods that were part of the public session.

NUMBER OF SOURCE DOCUMENTS

Under contract to the Agency for Healthcare Research and Quality (AHRQ), the Johns Hopkins University Evidence-based Practice Center (EPC) identified and analyzed the following eligible studies (not including previous systematic reviews) to prepare the Evidence Report/Technology assessment, which was subsequently presented to the Consensus Development Panel team as a reference for discussion at the Conference.

Key question 1b (relation of initial biopsy results to treatment outcomes): 21

Key question 1e (use of tests to predict biopsy findings): 66

Key questions 2a/2c (treatment options): 46 (16 pertained to key question 2a, and 30 pertained to key question 2c)

Key question 2d (long-term outcomes of current treatment outcomes): 40

Key questions 3a/3b (screening for hepatocellular carcinoma): 1 was relevant to key question 3a, and 23 studies were relevant to key question 3b

Note from the Johns Hopkins University Evidence-based Practice Center (EPC): the total number of articles pertaining to key questions exceeded the number of articles reviewed because some articles were identified as relevant for more than one key question.

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

Expert Consensus
Weighting According to a Rating Scheme (Scheme Given)

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Paired reviewers from the Johns Hopkins University Evidence-based Practice Center, under contract to the Agency for Healthcare Research and Quality (AHRQ), assessed the quality of each eligible study in terms of representativeness of the study population, bias and confounding, description of therapy/management, outcomes and follow-up, and statistical quality and interpretation. The score for each category of study quality was the percentage of the total points available in each category for that study and could range from zero to 100 percent. The total quality score was the average of the five categorical scores. In addition, the reviewers also completed an item on potential conflict of interest.

Evidence Grades

Grade A (strong): Appropriate data available, including at least one well done randomized controlled trial; study population sufficiently large; adequate controls; data consistent; intervention clearly superior, equivalent or inferior to another strategy

Grade B (moderate): Appropriate data available; study population sufficiently large; adequate controls; data reasonably consistent; intervention data indicate superiority or equivalence of one intervention compared to another; intervention likely to be superior, equivalent, or inferior to another but insufficient evidence to conclude definitely

Grade C (weak): Some data available; study population reasonably large; data indicate trend supporting benefit (or equivalence) of one intervention compared to another; insufficient evidence to conclude that intervention is likely to be superior, equivalent or inferior to another

Grade I (insufficient): Appropriate data not available or insufficient number of patients studied

## METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Under contract to the Agency for Healthcare Research and Quality (AHRQ), the Johns Hopkins University Evidence-based Practice Center (EPC) constructed evidence tables to present the information obtained on each key question to the Consensus Development Panel. For each key question, the Evidence-based Practice Center team created a set of four tables, the first presenting basic information about study aims and eligibility criteria, the second presenting selected characteristics of study participants, the third presenting assessments of study quality, and the fourth presenting selected results most pertinent to the key question.

### METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Consensus Development Conference)

### DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

During the first day and-a-half of the National Institutes of Health (NIH) conference, experts presented the latest hepatitis C research findings to an independent non-Federal Consensus Development Panel. After weighing this scientific evidence, the panel drafted a statement, addressing key questions. On the final day of the conference, the panel chairperson read the draft statement to the conference audience and invited comments and questions.

### 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

The Consensus Development Panel´s draft statement was posted to the Consensus Program Web site (http://consensus.nih.gov) on Wednesday, June 12, 2002, and final statement revisions were made on September 12, 2002.

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

Conclusions

The incidence of newly acquired hepatitis C infection has diminished in the United States. This decline is largely due to a decrease in cases among injection-drug users (IDUs) for reasons that are unclear and, to a lesser extent, to testing of blood donors for hepatitis C virus (HCV). The virus is transmitted by blood and such transmission now occurs primarily through injection drug use, sex with an infected partner or multiple partners, and occupational exposure. The majority of infections become chronic, and therefore the prevalence of HCV infections is high, with about 3 million Americans now estimated to be chronically infected. HCV is a leading cause of cirrhosis, a common cause of hepatocellular carcinoma (HCC) and the leading cause of liver transplantation in the United States. The disease spectrum associated with HCV infection varies greatly. Various studies have suggested that 3 to 20 percent of chronically infected patients will develop cirrhosis over a 20-year period, and these patients are at risk for HCC. Persons who are older at the time of infection, patients with continuous exposure to alcohol, and those co-infected with human immunodeficiency virus (HIV) or hepatitis b virus (HBV) demonstrate accelerated progression to more advanced liver disease. Conversely, individuals infected at a younger age have little or no disease progression over several decades.

The diagnosis of chronic hepatitis C infection is often suggested by abnormalities in alanine aminotransferase (ALT) levels and is established by enzyme immunoassay (EIA) followed by confirmatory determination of hepatitis C virus (HCV) ribonucleic acid (RNA). Several sensitive and specific assays are now partly automated for the purposes of detecting HCV RNA and quantifying the viral level. Although there is little correlation between viral level and disease manifestations, these assays have proven useful in identifying those patients who are more likely to benefit from treatment and, particularly, in demonstrating successful response to treatment as defined by a sustained virological response (SVR). Liver biopsy is useful in defining baseline abnormalities of liver disease and in enabling patients and healthcare providers to reach a decision regarding antiviral therapy. Noninvasive tests do not currently provide the information that can be obtained through liver biopsy. Information on the genotype of the virus is important to guide treatment decisions. Genotype 1, most commonly found in the United States, is less amenable to treatment than genotypes 2 or 3. Therefore, clinical trials of antiviral therapies require genotyping information for appropriate stratification of subjects.

Recent therapeutic trials in defined, selected populations have clearly shown that combinations of interferons and ribavirin are more effective than monotherapy. Moreover, trials using pegylated interferons have yielded improved SVR rates with similar toxicity profiles. However, results continue to show that the SVR rate is less common in patients with genotype 1 infections, higher HCV RNA levels, or more advanced stages of fibrosis. Genotype 1 infections require therapy for 48 weeks, whereas shorter treatment is feasible in genotype 2 and 3 infections. In genotype 1, the lack of an early virologic response (< 2 log decrease in HCV RNA) is associated with failure to achieve an SVR. The SVR is lower in patients with advanced liver disease than in patients without cirrhosis.

Ongoing trials are exploring the usefulness of combination therapy in various populations. Preliminary experience in injection-drug users (IDUs), individuals co-infected with human immunodeficiency virus (HIV), children, and other special groups suggests similar responses are achievable in these populations. Patients

with acute hepatitis C may be treated, but specific recommendations for antiviral treatment must await further evaluation of the rate of spontaneous clearance of the virus and determination of the optimal time to initiate treatment.

Preventive measures beyond blood-banking practices include prompt identification of infected individuals, awareness of the potential for perinatal transmission, implementation of safe-injection practices, linkage of drug users to drug treatment programs, and implementation of community-based education and support programs to modify risk behavior. Some of these measures have been successfully implemented in the control of human immunodeficiency virus (HIV) infections, and it stands to reason that they would be valuable for reducing HCV transmission.

Future advances in the diagnosis and management of hepatitis C require continued vigilance concerning the transmission of this infection, extending treatment to populations not previously evaluated in treatment trials, and the introduction of more effective therapies.

## Recommendations

- Educate the American public on the transmission of HCV in order to better identify affected individuals and to institute preventive measures.
- Develop reliable, reproducible, and efficient culture systems for propagating HCV and expand basic research in the pathogenic mechanisms underlying hepatic fibrosis.
- Promote the standardization and wide availability of diagnostic tests for HCV infection and its complications, leading to early diagnosis and the implementation of appropriate treatment practices.
- Promote the establishment of screening tests for all groups at high risk of HCV infection, including injection-drug users and incarcerated individuals.
- Expand the delineation of disease manifestations, noninvasive tests, and the role of the liver biopsy, so that the application of current treatment practices may be refined.
- Establish a Hepatitis Clinical Research Network for the purpose of conducting research related to the natural history, prevention, and treatment of hepatitis C.
- Organize randomized controlled trials (RCTs) to extend treatment to special populations not represented in current clinical trials and to determine the applicability of accepted antiviral drug combinations to populations such as children and adolescents, and patients with acute hepatitis. Effective approaches are needed for drug users receiving drug treatment, alcohol abusers, prisoners, patients with stabilized depression, those with co-infection with human immunodeficiency virus, patients with decompensated cirrhosis, and HCV infections in transplant recipients. Such efforts should lead to decreased morbidity and mortality from the disease, as well as a decrease in the reservoir of disease.
- Institute measures to reduce transmission of HCV among injection-drug users, including providing access to sterile syringes through needle exchange, physician prescription, and pharmacy sales; and expanding the Nation's capacity to provide treatment for substance abuse. Physicians and pharmacists should be educated to recognize that providing injection-drug

users with access to sterile syringes and education in safe injection practices may be lifesaving.
- Evaluate strategies to interrupt mother-to-infant transmission of HCV.
- Compare new therapies to current treatments in nonresponders, to include not just antiviral agents but also combinations of antifibrotic drugs, immunomodulatory agents, and alternative therapies.
- Encourage a comprehensive approach to promote the collaboration among health professionals concerned with management of addiction, primary care physicians, and specialists involved in various aspects of HCV - to deal with the complex societal, medical, and psychiatric issues of injection-drug users afflicted by the disease.
- Seek appropriate support from governmental agencies and the private sector to address urgent research questions concerning the epidemiology and treatment of this disease.

### CLINICAL ALGORITHM(S)

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The panel, answering predefined questions, developed their conclusions based on the scientific evidence presented in open forum and the scientific literature.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

#### Overall Benefits

- Appropriate diagnostic/prognostic evaluation/testing of patients with suspected or confirmed hepatitis C virus (HCV) infection
- Appropriate and effective management/treatment of hepatitis C in various populations
- Decreased morbidity and mortality related to hepatitis C, as well as a decrease in the reservoir of disease
- Reduced transmission of HCV

#### Specific Benefits

- Several sensitive and specific assays have proven useful in identifying those patients who are more likely to benefit from treatment and, particularly, in demonstrating successful response to treatment as defined by a sustained virological response (SVR).
- Liver biopsy is useful in defining baseline abnormalities of liver disease and in enabling patients and healthcare providers to reach a decision regarding antiviral therapy.
- Information on the genotype of the virus helps guide treatment decisions.

- Recent therapeutic trials in defined, selected populations have clearly shown that combinations of interferons and ribavirin are more effective than monotherapy. Moreover, trials using pegylated interferons have yielded improved SVR rates with similar toxicity profiles.

### POTENTIAL HARMS

- Side effects of medications. In registration trials of pegylated interferon and ribavirin, significant side effects resulted in discontinuation of treatment in approximately 10 to 14 percent of patients. Major side effects of combination therapy include influenza-like symptoms, hematologic abnormalities, and neuropsychiatric symptoms. Psychological conditions, particularly depression, are common among persons with hepatitis C and are frequent side effects of interferon. Severe hemolysis from ribavirin may occur in patients with renal insufficiency. Lactic acidosis may be a rare complication of combination therapy in patients undergoing therapy for human immunodeficiency virus (HIV) and hepatitis C virus (HCV).
- False findings for enzyme immunoassays (EIAs). Enzyme immunoassay can result in false-positive and false-negative findings.
- Adverse effects of screening for hepatocellular carcinoma. Studies of the performance characteristics of alpha-fetoprotein (AFP) and hepatic ultrasound show that alpha-fetoprotein has a poor sensitivity and a high rate of false-positive reactions. Hepatic ultrasound can lead to invasive and unnecessary evaluations of lesions (e.g., regenerative nodules, hemangiomas, hepatic cysts) that are not hepatocellular carcinoma (HCC).

#### Subgroups Most Likely to be Harmed:

- False-negative enzyme immunoassay (EIAs) rarely occur in patients on hemodialysis and patients with immune deficiencies.
- False-positive enzyme immunoassays may occur in patients with autoimmune disorders.

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

- This statement is an independent report of the consensus panel and is not a policy statement of the National Institutes of Health (NIH) or the Federal Government.
- The statement reflects the panel's assessment of medical knowledge available at the time the statement was written. Thus, it provides a "snapshot in time" of the state of knowledge on the conference topic. When reading the statement, keep in mind that new knowledge is inevitably accumulating through medical research.

## 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

Living with Illness
Staying Healthy

### IOM DOMAIN

Effectiveness
Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

National Institutes of Health (NIH). Management of hepatitis C: 2002. Rockville (MD): National Institutes of Health (NIH); 2002 Aug 26. 44 p.

### ADAPTATION

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

### DATE RELEASED

1997 Mar (revised 2002 Aug 26)

### GUIDELINE DEVELOPER(S)

National Institutes of Health (NIH) Consensus Development Panel on Management of Hepatitis C - Independent Expert Panel

### GUIDELINE DEVELOPER COMMENT

NIH Consensus Statements are prepared by a nonadvocate, non-Federal panel of experts, based on (1) presentations by investigators working in areas relevant to the consensus questions during a 2-day public session; (2) questions and statements from conference attendees during open discussion periods that are part of the public session; and (3) closed deliberations by the panel during the remainder of the second day and morning of the third. This statement is an independent report of the panel and is not a policy statement of the NIH or the Federal Government.

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the NIH Office of Medical Applications of Research (OMAR) sponsored the conference. Co-sponsors included the National Cancer Institute (NCI), the

National Center for Complementary and Alternative Medicine (NCCAM), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute of Child Health and Human Development (NICHD), the National Institute on Drug Abuse (NIDA), the Centers for Disease Control and Prevention (CDC), the Centers for Medicare and Medicaid Services (CMS), the U.S. Department of Veterans Affairs (VA), and the U.S. Food and Drug Administration (FDA).

The Agency for Healthcare Research and Quality (AHRQ) provided support to the NIH Consensus Development Conference on Management of Hepatitis C: 2002 through its Evidence-based Practice Center program. Under contract to the AHRQ, the Johns Hopkins University Evidence-based Practice Center developed the systematic review and analysis that served as a reference for discussion at the Conference

## SOURCE(S) OF FUNDING

United States Government

## GUIDELINE COMMITTEE

National Institutes of Health (NIH) Consensus Development Panel

## COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

The 12-member consensus panel included representation from internal medicine, gastroenterology, infectious diseases, pediatrics, family practice, oncology and the public.

Panel Members: James L. Boyer, MD; (Panel and Conference Chairperson); Eugene B. Chang, MD; Deborah E. Collyar; Laurie D. DeLeve, MD, PhD; Judith Feinberg, MD; Thomas A. Judge, MD; Franco M. Muggia, MD; Charles L. Shapiro, MD; Stephen A. Spector, MD; Frederick J. Suchy, MD; Patricia L. Tomsko, MD, CMD; Barbara J. Turner, MD, MS Ed

## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All of the panelists who participated in the National Institutes of Health (NIH) conference and contributed to the writing of this consensus statement were identified as having no financial or scientific conflict of interest, and all signed conflict of interest forms attesting to this fact.

## GUIDELINE STATUS

This is the current release of the guideline. This guideline updates a previously issued version (NIH Consens Statement Online 1997 Mar 24-26;15[3]:1-41).

An update is not in progress at this time.

## GUIDELINE AVAILABILITY

Electronic copies: Available from the National Institutes of Health (NIH) Consensus Development Conference Program Web site. Also available from the National Library of Medicine Health Services/Technology Assessment Text (HSTAT) Web site.

Print copies: Available from the NIH Consensus Development Program Information Center, PO Box 2577, Kensington, MD 20891; Toll free phone (in U.S.), 1-888-NIH-CONSENSUS (1-888-644-2667); autofax (in U.S.), 1-888-NIH-CONSENSUS (1-888-644-2667); e-mail: consensus_statements@mail.nih.gov.

## AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- A complete bibliography prepared by the National Library of Medicine (NLM) is available at the NLM Web site
- Management of chronic hepatitis C. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ), 2002 Jun. (Evidence report/technology assessment: no. 60). AHRQ Publication No. 02-E029. Available from the AHRQ Web site: Summary; File Download.
- Speaker Abstracts – available in Portable Document Format (PDF) from the National Institutes of Health (NIH) Consensus Development Conference Program Web site.
- NIH News Release - Progress and Future Directions for Management of Hepatitis C.

## PATIENT RESOURCES

None available

## NGC STATUS

This summary was completed by ECRI on August 1, 1998. The information was verified by the guideline developer on December 1, 1998. This summary was updated by ECRI on December 17, 2002. The information was verified by the guideline developer on December 30, 2002.

## COPYRIGHT STATEMENT

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