Complete Summary

GUIDELINE TITLE

Screening for hepatitis B virus infection: recommendation statement.

BIBLIOGRAPHIC SOURCE(S)

U.S. Preventive Services Task Force (USPSTF). Screening for hepatitis B virus infection: recommendation statement. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2004 Feb. 4 p. [3 references]

GUIDELINE STATUS

This is the current release of the guideline.

This release updates a previously published guideline: U.S. Preventive Services Task Force. Guide to clinical preventive services. 2nd ed. Baltimore (MD): Williams & Wilkins; 1996. Chapter 24, Screening for hepatitis B virus infection. p. 269-76.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Hepatitis B virus infection

GUIDELINE CATEGORY

Prevention
Screening

CLINICAL SPECIALTY

Family Practice
Gastroenterology
Infectious Diseases
Internal Medicine
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To summarize the current U.S. Preventive Services Task Force (USPSTF) recommendations for the screening for Hepatitis B virus infection and the supporting scientific evidence
- To update the 1996 recommendations contained in the *Guide to Clinical Preventive Services*, Second Edition

TARGET POPULATION

- Children, adults, and pregnant women seen in primary care settings
- Infants born to women infected with hepatitis B virus

INTERVENTIONS AND PRACTICES CONSIDERED

Screening for hepatitis B virus (HBV) using the hepatitis B surface antigen (HBsAg) test

Interventions discussed but not specifically recommended:

1. Vaccinating all infants against HBV infection
2. Postexposure prophylaxis with hepatitis B immune globulin for infants born to HBV-infected mothers

MAJOR OUTCOMES CONSIDERED

Key Question 1: Is there new evidence of harms or reduced benefits from the universal screening of pregnant women?

Key Question 2: Is there new evidence that screening and immunizing the general population for hepatitis B virus (HBV) infection or that universal screening and immunizing infants and children can reduce the morbidity and mortality associated with the chronic carrier state of HBV infection?

Key Question 3: Is there new evidence of the benefits or harms associated with screening adolescents and high-risk individuals so they can be immunized against HBV?

Key Question 4: Is there evidence indicating that risk assessment tools to identify persons at high risk for HBV infection are valid?

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

This brief update is based on a review of English-language articles published in MEDLINE®, the Cochrane Library, and the National Guideline Clearinghouse™ between 1994 and 2001. The search was further limited to Abridged Index Medicus® publications The search reviewed direct evidence on the characteristics of screening tests and the benefits and harms of routine screening for hepatitis B virus infection (HBV), as well as the benefits and harms of screening individuals at high risk. The search identified new confirmatory evidence for the universal screening of pregnant women and for childhood immunization programs. Currently, there is limited evidence that screening and immunizing persons at high risk reduces the transmission or the population incidence of hepatitis B virus infection.

The search was limited to randomized controlled trials (RCTs), meta-analyses, systematic reviews, editorials, and commentaries concerning the key questions. The populations considered were pregnant women, infants, asymptomatic individuals, and high-risk, asymptomatic persons. Studies were excluded if they did not meet the inclusion criteria or if they did not pertain to populations in the United States. No new RCTs, meta-analyses, or systematic reviews of the evidence for screening in the general population were found.

Search terms included hepatitis B, screening, pregnancy, infants, neonate, asymptomatic, immunization, general, high, risk, morbidity, mortality, liver, hepatocellular carcinoma, prevent as a truncated term, and universal. The Medical Subject Heading® (MeSH®) terms Hepatitis B and screening were exploded, while the remaining terms were used for free-text searches. The search yielded no RCTs meeting the inclusion criteria, 12 review articles, and 1 observational study. Only one article directly addressed one of the key questions.

NUMBER OF SOURCE DOCUMENTS

Key Question 1 = 0 studies
Key Question 2 = 1 studies
Key Question 3 = 0 studies
Key Question 4 = 0 studies

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The U.S. Preventive Services Task Force (USPSTF) grades the quality of the overall evidence for a service on a 3-point scale (good, fair, poor):

Good

Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

Fair

Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes.

Poor

Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Balance Sheets
Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

When the overall quality of the evidence is judged to be good or fair, the U.S. Preventive Services Task Force (USPSTF) proceeds to consider the magnitude of net benefit to be expected from implementation of the preventive service. Determining net benefit requires assessing both the magnitude of benefits and the magnitude of harms and weighing the two.

The USPSTF classifies benefits, harms, and net benefits on a 4-point scale: "substantial," "moderate," "small," and "zero/negative."

"Outcomes tables" (similar to "balance sheets") are the USPSTF's standard resource for estimating the magnitude of benefit. These tables, prepared by the topic teams for use at USPSTF meetings, compare the condition specific outcomes expected for a hypothetical primary care population with and without use of the preventive service. These comparisons may be extended to consider only people of specified age or risk groups or other aspects of implementation. Thus, outcomes tables allow the USPSTF to examine directly how the preventive service affects benefits for various groups.

When evidence on harms is available, the topic teams assess its quality in a manner like that for benefits and include adverse events in the outcomes tables. When few harms data are available, the USPSTF does not assume that harms are small or nonexistent. It recognizes a responsibility to consider which harms are likely and judge their potential frequency and the severity that might ensue from implementing the service. It uses whatever evidence exists to construct a general confidence interval on the 4-point scale (e.g., substantial, moderate, small, and zero/negative).

Value judgments are involved in using the information in an outcomes table to rate either benefits or harms on the USPSTF's 4-point scale. Value judgments are also needed to weigh benefits against harms to arrive at a rating of net benefit.

In making its determinations of net benefit, the USPSTF strives to consider what it believes are the general values of most people. It does this with greater confidence for certain outcomes (e.g., death) about which there is little disagreement about undesirability, but it recognizes that the degree of risk people are willing to accept to avert other outcomes (e.g., cataracts) can vary considerably. When the USPSTF perceives that preferences among individuals vary greatly, and that these variations are sufficient to make a trade-off of benefits and harms a "close-call," then it will often assign a C recommendation (see the "Recommendation Rating Scheme" field). This recommendation indicates the decision is likely to be sensitive to individual patient preferences.

The USPSTF uses its assessment of the evidence and magnitude of net benefit to make recommendations. The general principles the USPSTF follows in making recommendations are outlined in Table 5 of the companion document cited below. The USPSTF liaisons on the topic team compose the first drafts of the recommendations and rationale statements, which the full panel then reviews and edits. Recommendations are based on formal voting procedures that include explicit rules for determining the views of the majority.

From: Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow, CD, Teutsch SM, Atkins D. Current methods of the U.S. Preventive Services Task Force: a review of the process. Methods Work Group, Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):21-35.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations according to one of five classifications (A, B, C, D, I) reflecting the strength of evidence and magnitude of net benefit (benefits minus harms):

A

The USPSTF strongly recommends that clinicians provide [the service] to eligible patients. The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.

B

The USPSTF recommends that clinicians provide [the service] to eligible patients. The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.

C

The USPSTF makes no recommendation for or against routine provision of [the service]. The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.

D

The USPSTF recommends against routinely providing [the service] to asymptomatic patients. The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.

I

The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. Evidence that [the service] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined.

COST ANALYSIS

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

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Peer Review. Before the U.S. Preventive Services Task Force (USPSTF) makes its final determinations about recommendations on a given preventive service, the Evidence-based Practice Center (EPC) and the Agency for Healthcare Research and Quality (AHRQ) send a draft systematic evidence review to 4 to 6 external experts and to federal agencies and professional and disease-based health organizations with interests in the topic. They ask the experts to examine the review critically for accuracy and completeness and to respond to a series of specific questions about the document. After assembling these external review comments and documenting the proposed response to key comments, the topic team presents this information to the Task Force in memo form. In this way, the Task Force can consider these external comments and a final version of the systematic review before it votes on its recommendations about the service. Draft recommendations are then circulated for comment from reviewers representing professional societies, voluntary organizations, and federal agencies. These comments are discussed before the whole U.S. Preventive Services Task Force before final recommendations are confirmed.

Recommendations of Others. Recommendations regarding screening for Hepatitis B virus infection were considered from the following groups: the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, and the American College of Physicians-American Society of Internal Medicine.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations (A, B, C, D, or I) and the quality of the overall evidence for a service (good, fair, poor). The definitions of these grades can be found at the end of the "Major Recommendations" field.

The U.S. Preventive Services Task Force (USPSTF) strongly recommends screening for hepatitis B virus (HBV) infection in pregnant women at their first prenatal visit. **A Recommendation.**

The USPSTF found good evidence that universal prenatal screening for HBV infection using hepatitis B surface antigen (HBsAg) substantially reduces prenatal transmission of HBV and the subsequent development of chronic HBV infection. The current practice of vaccinating all infants against HBV infection and postexposure prophylaxis with hepatitis B immune globulin administered at birth to infants of HBV-infected mothers substantially reduces the risk for acquiring HBV infection.

The USPSTF recommends against routinely screening the general asymptomatic population for chronic hepatitis B virus infection. **D Recommendation.**

The USPSTF found no evidence that screening the general population for HBV infection improves long-term health outcomes such as cirrhosis, hepatocellular carcinoma, or mortality. The prevalence of HBV infection is low; the majority of

infected individuals do not develop chronic infection, cirrhosis, or HBV-related liver disease. Potential harms of screening include labeling, although there is limited evidence to determine the magnitude of this harm. As a result, the USPSTF concluded that the potential harms of screening for HBV infection in the general population are likely to exceed any potential benefits.

Clinical Considerations

- Routine hepatitis vaccination has had significant impact in reducing the number of new HBV infections per year, with the greatest decline among children and adolescents. Programs that vaccinate health care workers also reduce the transmission of HBV infection.
- Most people who become infected as adults or older children recover fully from HBV infection and develop protective immunity to the virus.
- The main risk factors for HBV infection in the United States include diagnosis with a sexually transmitted disease, intravenous drug use, sexual contact with multiple partners, male homosexual activity, and household contacts of chronically infected persons. However, screening strategies to identify individuals at high risk have poor predictive value, since 30 to 40 percent of infected individuals do not have any easily identifiable risk factors.
- Important predictors of progressive HBV infection include longer duration of infection and the presence of comorbid conditions such as alcohol abuse, HIV, or other chronic liver disease. Individuals with HBV infection identified through screening may benefit from interventions designed to reduce liver injury from other causes, such as counseling to avoid alcohol abuse and immunization against hepatitis A. However, there is limited evidence on the effectiveness of these interventions.

Definitions:

Strength of Recommendations

The USPSTF grades its recommendations according to one of five classifications (A, B, C, D, I) reflecting the strength of evidence and magnitude of net benefit (benefits minus harms):

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Strength of Evidence

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Poor

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CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is identified in the "Major Recommendations" field.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

The U.S. Preventive Services Task Force found good evidence that universal prenatal screening for hepatitis B virus (HBV) infection using hepatitis B surface antigen (HBsAg) substantially reduces prenatal transmission of HBV and the subsequent development of chronic HBV infection.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The U.S. Preventive Services Task Force recommendations are independent of the U.S. government. They should not be construed as an official position of Agency for Healthcare Research and Quality (AHRQ) or the U.S. Department of Health and Human Services.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The experiences of the first and second U.S. Preventive Services Task Force (USPSTF), as well as that of other evidence-based guideline efforts, have highlighted the importance of identifying effective ways to implement clinical recommendations. Practice guidelines are relatively weak tools for changing clinical practice when used in isolation. To effect change, guidelines must be coupled with strategies to improve their acceptance and feasibility. Such strategies include enlisting the support of local opinion leaders, using reminder systems for clinicians and patients, adopting standing orders, and audit and feedback of information to clinicians about their compliance with recommended practice.

In the case of preventive services guidelines, implementation needs to go beyond traditional dissemination and promotion efforts to recognize the added patient and clinician barriers that affect preventive care. These include clinicians' ambivalence about whether preventive medicine is part of their job, the psychological and practical challenges that patients face in changing behaviors, lack of access to health care or of insurance coverage for preventive services for some patients, competing pressures within the context of shorter office visits, and the lack of organized systems in most practices to ensure the delivery of recommended preventive care.

Dissemination strategies have changed dramatically in this age of electronic information. While recognizing the continuing value of journals and other print formats for dissemination, the Agency for Healthcare Research and Quality will make all U.S. Preventive Services Task Force (USPSTF) products available through its Web site. The combination of electronic access and extensive material in the public domain should make it easier for a broad audience of users to access U.S. Preventive Services Task Force materials and adapt them for their local needs. Online access to U.S. Preventive Services Task Force products also opens up new possibilities for the appearance of the annual, pocket-size *Guide to Clinical Preventive Services*.

To be successful, approaches for implementing prevention have to be tailored to the local level and deal with the specific barriers at a given site, typically requiring the redesign of systems of care. Such a systems approach to prevention has had notable success in established staff-model health maintenance organizations, by addressing organization of care, emphasizing a philosophy of prevention, and altering the training and incentives for clinicians. Staff-model plans also benefit from integrated information systems that can track the use of needed services and generate automatic reminders aimed at patients and clinicians, some of the most consistently successful interventions. Information systems remain a major challenge for individual clinicians' offices, however, as well as for looser affiliations of practices in network-model managed care and independent practice associations, where data on patient visits, referrals, and test results are not always centralized.

IMPLEMENTATION TOOLS

Foreign Language Translations
Patient Resources
Pocket Guide/Reference Cards

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

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

U.S. Preventive Services Task Force (USPSTF). Screening for hepatitis B virus infection: recommendation statement. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2004 Feb. 4 p. [3 references]

ADAPTATION

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

DATE RELEASED

1996 (revised 2004 Feb 24)

GUIDELINE DEVELOPER(S)

United States Preventive Services Task Force - Independent Expert Panel

GUIDELINE DEVELOPER COMMENT

The U.S. Preventive Services Task Force (USPSTF) is a federally-appointed panel of independent experts. Conclusions of the U.S. Preventive Services Task Force do not necessarily reflect policy of the U.S. Department of Health and Human Services (DHHS) or its agencies.

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

U.S. Preventive Services Task Force (USPSTF)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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**Member of the USPSTF at the time this recommendation was finalized.* For a list of current Task Force members, go to www.ahrq.gov/clinic/uspstfab.htm.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The U.S. Preventive Services Task Force (USPSTF) has an explicit policy concerning conflict of interest. All members and Evidence-based Practice Center (EPC) staff disclose at each meeting if they have an important financial conflict for each topic being discussed. Task Force members and EPC staff with conflicts can participate in discussions about evidence, but members abstain from voting on recommendations about the topic in question.

From: Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow, CD, Teutsch SM, Atkins D. Current methods of the U.S. Preventive Services Task Force: a review of the process. Methods Work Group, Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):21-35.

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This release updates a previously published guideline: U.S. Preventive Services Task Force. Guide to clinical preventive services. 2nd ed. Baltimore (MD): Williams & Wilkins; 1996. Chapter 24, Screening for hepatitis B virus infection. p. 269-76.

GUIDELINE AVAILABILITY

Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site.

Print copies: Available from the Agency for Healthcare Research and Quality (AHRQ) Publications Clearinghouse. For more information, go to http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only).

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

Evidence Reviews:

- Screening for hepatitis B virus infection: a brief evidence update for the U.S. Preventive Services Task Force. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ), 2004 Feb. 5 p.

Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site.

Background Articles:

- Woolf SH, Atkins D. The evolving role of prevention in health care: contributions of the U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):13-20.
- Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow, CD, Teutsch SM, Atkins D. Current methods of the U.S. Preventive Services Task Force: a review of the process. Methods Work Group, Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):21-35.
- Saha S, Hoerger TJ, Pignone MP, Teutsch SM, Helfand M, Mandelblatt JS. The art and science of incorporating cost effectiveness into evidence-based recommendations for clinical preventive services. Cost Work Group of the Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):36-43.

Electronic copies: Available from U.S. Preventive Services Task Force (USPSTF) Web site.

The following are also available:

- The guide to clinical preventive services, 2006. Recommendations of the U.S. Preventive Services Task Force. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ), 2006. 228 p. Electronic copies available from the AHRQ Web site.
- A step-by-step guide to delivering clinical preventive services: a systems approach. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ), 2002 May. 189 p. Electronic copies available from the AHRQ Web site. See the related QualityTool summary on the Health Care Innovations Exchange Web site.

Print copies: Available from the Agency for Healthcare Research and Quality Publications Clearinghouse. For more information, go to http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only).

The Electronic Preventive Services Selector (ePSS), available as a PDA application and a web-based tool, is a quick hands-on tool designed to help primary care clinicians identify the screening, counseling, and preventive medication services that are appropriate for their patients. It is based on current recommendations of the USPSTF and can be searched by specific patient characteristics, such as age, sex, and selected behavioral risk factors.

PATIENT RESOURCES

The following is available:

- The pocket guide to good health for adults. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2003.

  Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site. Copies also available in Spanish from the USPSTF Web site. See the related QualityTool summary on the Health Care Innovations Exchange Web site.

  Print copies: Available from the Agency for Healthcare Research and Quality (AHRQ) Publications Clearinghouse. For more information, go to http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only).

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on June 30, 1998. The information was verified by the guideline developer on December 1, 1998. This summary was updated by ECRI on April 8, 2004. The updated information was verified by the guideline developer on April 22, 2004.

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