

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

NIH Consensus Development Conference: Management of Hepatitis B; Notice

Notice is hereby given of the National Institutes of Health (NIH) "NIH Consensus Development Conference: Management of Hepatitis B" to be held October 20–22, 2008, in the NIH Natcher Conference Center, 45 Center Drive, Bethesda, Maryland 20892. The conference will begin at 8:30 a.m. on October 20 and 21, and at 9 a.m. on October 22, and will be open to the public.

Hepatitis B is a major cause of liver disease worldwide, ranking as a substantial cause of cirrhosis and liver cancer. In the United States, about 1.25 million people are chronically infected with the virus, resulting in 3,000 to 5,000 deaths each year. However, this condition occurs more frequently in high risk groups, including Asian Americans, emigrants from areas of the world where hepatitis B is common (China, Korea, Southeast Asia, the Indian Subcontinent, Africa, and Micronesia), men who have sex with men, injection drug users, and recipients of blood and blood products before screening procedures with enhanced sensitivity were implemented in 1986. Since routine hepatitis B vaccination of U.S. children began in 1991, new cases of acute hepatitis B among children and adolescents have dropped by more than 95 percent—and by 75 percent across all age groups. In nonprotected individuals, transmission can result from exposure to infectious blood or body fluids containing blood. A major impediment to diagnosis is that many infected individuals are either asymptomatic or experience only nonspecific symptoms of disease, such as fatigue or muscle ache.

For approximately 90 percent of adults, acute infection with the hepatitis B virus is resolved by the body's immune system and does not cause long-term problems. The transition from acute to chronic infection appears to occur when the immune system does not effectively destroy and clear virus-infected cells. This leads to high blood levels of both hepatitis B DNA and antigens, as well as antibodies produced by the body in an attempt to combat the infection. The natural history of the disease is not well understood, however, which makes management of this complex disease challenging.

Many factors can influence treatment decisions for an individual patient, including age, ALT (alanine aminotransferase, a liver enzyme) level, viral load, liver biopsy results, and the presence of a co-infecting virus (i.e., HIV). Treatment decisions require in-depth analysis of multiple blood test results, which are typically repeated at regular intervals to monitor the disease course. There are currently six approved therapeutic agents: interferon-alpha, lamivudine, adefovir dipivoxil, entecavir, pegylated interferon, and telbivudine, which are often used in combination. Generally, these drugs act to decrease the risk of liver damage from hepatitis B by slowing or stopping the replication of the virus.

Questions remain as to which groups of patients benefit from therapy and at which point in the course of their disease. Specific recommendations for hepatitis B therapy are limited by a lack of reliable long-term safety and efficacy information. This is a difficult decision for physicians and patients, as treatments are expensive and may have bothersome, if not harmful, effects on patients. Left untreated, however, chronic hepatitis B can lead to liver failure and other serious liver problems. To examine these important issues, the National Institute of Diabetes and Digestive and Kidney Diseases and the Office of Medical Applications of Research of the National Institutes of Health will convene a Consensus Development Conference from October 20 to 22, 2008, to assess the available scientific evidence related to the following questions:

- What is the current burden of hepatitis B?
- What is the natural history of hepatitis B?
- What are the benefits and risks of the current therapeutic options for hepatitis B?
- Which persons with hepatitis B should be treated?
- What measures are appropriate to monitor therapy and assess outcomes?
- What are the greatest needs and opportunities for future research on hepatitis B?

An impartial, independent panel will be charged with reviewing the available published literature in advance of the conference, including a systematic literature review commissioned through the Agency for Healthcare Research and Quality. The first day and a half of the conference will consist of presentations by expert researchers and practitioners and open public discussions. On Wednesday, October 22, the panel will present a statement of its collective assessment of the evidence to answer

each of the questions above. The panel will also hold a press conference to address questions from the media. The draft statement will be published online later that day, and the final version will be released approximately six weeks later. The primary sponsors of this meeting are the NIH National Institute of Diabetes and Digestive and Kidney Diseases and the NIH Office of Medical Applications of Research.

Advance information about the conference and conference registration materials may be obtained from American Institutes for Research of Silver Spring, Maryland, by calling 888-644-2667, or by sending e-mail to consensus@mail.nih.gov. American Institutes for Research's mailing address is 10720 Columbia Pike, Silver Spring, MD 20901. Registration information is also available on the NIH Consensus Development Program Web site at <http://consensus.nih.gov>.

Please Note: The NIH has instituted security measures to ensure the safety of NIH employees and property. All visitors must be prepared to show a photo ID upon request. Visitors may be required to pass through a metal detector and have bags, backpacks, or purses inspected or x-rayed as they enter NIH buildings. For more information about the security measures at NIH, please visit the Web site at <http://www.nih.gov/about/visitorsecurity.htm>.

Dated: August 4, 2008.

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Notice of Listing of Members of the National Institutes of Health's Senior Executive Service 2008 Performance Review Board

The National Institutes of Health (NIH) announces the persons who will serve on the National Institutes of Health's Senior Executive Service 2008 Performance Review Board. This action is being taken in accordance with Title 5, U.S.C., Section 4314(c)(4), which requires that members of performance review boards be appointed in a manner to ensure consistency, stability, and objectivity in performance appraisals, and requires that notice of the appointment of an individual to serve as a member be published in the **Federal Register**.

The following persons will serve on the NIH Performance Review Board,