



Yesterday

- By 1970, the hepatitis B virus had been identified and shown to be a major cause of acute and chronic liver disease. Reliable but somewhat insensitive tests for the virus were newly available.
- Hepatitis B was the most common cause of acute liver disease in the United States with an estimated 200,000 to 300,000 persons infected annually with the hepatitis B virus, including approximately 20,000 children. The United States was in the midst of an epidemic of hepatitis B that lasted into the 1980s.
- Hepatitis B was a major cause of liver disease associated with blood transfusions. With the introduction of tests to detect hepatitis B in the screening of blood products, the rate of transfusion-associated hepatitis B began to decrease.
- In addition to blood transfusion, studies showed that hepatitis B could be spread by injection drug use and through sexual intercourse.
- The first hepatitis B virus vaccine was derived from human serum. It was found to be effective in preventing hepatitis in experimental animals, but it had yet to be tested in humans and there were major concerns about its safety, long-term efficacy, and cost.
- A growing body of evidence demonstrated that hepatitis B was a significant cause of chronic infections leading to liver disease, cirrhosis of the liver and liver cancer in about one fourth of carriers.
- Despite being able to diagnose chronic hepatitis B, there were no ways to prevent it from progressing to cirrhosis or developing into liver cancer. End-stage liver disease from hepatitis B was an untreatable and invariably fatal illness.
- There were no effective treatments for chronic hepatitis B. Corticosteroids were often prescribed, but subsequent studies would show that they were ineffective and potentially harmful.
- The World Health Organization listed hepatitis B among the top 10 causes of death in the world.

Today

- Over the past 40 years, major accomplishments have been achieved in the prevention, diagnosis, and treatment of chronic hepatitis B in the United States.
- Safe and effective recombinant hepatitis B vaccines are available and should be given to all newborns and children in the United States and many other countries throughout the world.
- Through public health programs to vaccinate Americans against hepatitis B, the rate of acute hepatitis B has fallen by more than 80 percent, with numbers of new cases at an all-time low. The disease is now virtually unknown in children born in the United States. Demonstration that the hepatitis B vaccine decreased chronic hepatitis B and cirrhosis in areas of the world where these diseases used to be common can be considered one of the great achievements of 20th century medicine.
- The widespread use of the hepatitis B vaccine has also appeared to decrease the rate of liver cancer, this being most noticeable in parts of the world where hepatitis B is common.
- Blood banks now screen all blood donations using sensitive tests for hepatitis B, as well as many other diseases. As a result, transfusion-associated hepatitis B has virtually disappeared in the United States.
- There is now a better understanding of the hepatitis B virus in terms of how it grows and how it affects patients. Sensitive tests for the virus help in evaluating patients for the seriousness of the infection and need for treatment.
- Several safe and effective antiviral treatments are now available for chronic hepatitis B. These treatments can control the disease in the majority of patients. The 2008 NIH Consensus Development Conference on Management of Hepatitis B (<http://consensus.nih.gov/2008/hepb.htm>) set forth medical evidence-based recommendations for therapy and gave recommendations for future research.
- If persons develop cirrhosis and end-stage liver disease from hepatitis B, they can be effectively

treated with liver transplantation. Because re-infection of the transplanted liver by the hepatitis B virus can now be prevented, the long-term survival after transplantation for hepatitis B is now excellent.

- In the United States, the combined use of the hepatitis B vaccine along with the currently available treatments for chronic hepatitis B has reduced the need for liver transplantation.
- However, chronic hepatitis B continues to affect an estimated 800,000 to 1.4 million people in the United States. Many of these persons are unaware of their infection. Challenges remain in identifying persons with chronic hepatitis B and providing them with sound recommendations for management and treatment.

Tomorrow

- Continued use of universal vaccination during childhood should promote further decreases in rates of hepatitis B in the United States. As a result, acute hepatitis B will become a disease that is rarely seen by physicians.
- Cases of chronic hepatitis B are also likely to become less frequent and most cases will be among immigrants from areas of the world where hepatitis B is common because vaccination has not been widely used. A policy of screening of immigrants for hepatitis B is likely to be implemented to help reduce the burden of this disease.
- Combined use of the hepatitis B vaccine and anti-viral treatments will greatly reduce the need for liver transplantation for hepatitis B. Furthermore, the rate of liver cancer due to hepatitis B should fall considerably.
- The NIH continues to support meritorious research focused on enhancing our understanding of disease mechanisms and developing better approaches to treatment and prevention that are expected to result in further improvements in hepatitis B management and control.
- Research supported by NIH continues to address areas to further our understanding of the hepatitis B virus. NIH-funded scientists are testing novel antiviral drugs, therapeutic vaccines, molecules that modulate the immune response, and are utilizing recently developed animal models.

- The NIH has launched the Hepatitis B Research Network (<http://www.hepbnet.org/>), a multi-center Network charged with advancing our understanding of disease processes and natural history, as well as to test the safety and efficacy of approaches using currently available drugs to treat and control hepatitis B. The Network plans to develop several clinical studies in both adults and children, and to apply state-of-the-art virologic and immunologic research techniques to understanding the factors that determine the course and outcome of hepatitis B.
- Clinical trials of new approaches to treat hepatitis B, including use of antiviral drugs in combination, are also conducted by scientists at the NIH Clinical Center in Bethesda, MD.
- In 2010, the Institute of Medicine published a report on “Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C” that provides a blueprint for the public health response to viral hepatitis in the United States, aimed at reducing the burden of hepatitis B and C. The U.S. Department of Health and Human Services has responded to this challenge and is putting in place a plan to carry out these recommendations, some of which are for future research components that are the focus of scientists at the NIH who have joined the Department’s Interagency Viral Hepatitis Working Group.
- In the future, hepatitis B will no longer be a major cause of death worldwide. Indeed, the World Health Organization is likely to develop a long-range program aimed at worldwide eradication of hepatitis B.

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National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK): <http://www2.niddk.nih.gov/>

National Institute of Allergy and Infectious Diseases (NIAID) Viral Hepatitis Research:
<http://www.niaid.nih.gov/topics/hepatitis/research/pages/introduction.aspx>