

06-ID-09

Committee: Infectious Diseases

Title: Chronic Hepatitis B Virus Infection

Statement of the Problem:

In the United States, an estimated 1.25 million persons have chronic hepatitis B virus (HBV) infection. Fifteen to 25% of these persons will develop the complications of cirrhosis or hepatocellular carcinoma. In addition, chronically infected persons are a major reservoir of transmission to others. Persons who test positive for the presence of hepatitis B surface antigen (HBsAg), HBeAg or HBV DNA are potentially infectious to household, sexual, and needle-sharing contacts. In order for a person to meet the current case definition for chronic HBV infection, the state or local health department must receive the positive results from two HBsAg tests conducted at least 6 months apart. For many health departments, only a small percentage of reported persons meet this criteria, resulting in a potentially significant undercount of chronic HBV cases in their jurisdiction. States and counties need a case definition that will accurately identify true cases of chronic infection in order to monitor the disease burden, develop prevention programs, and provide educational follow-up and referral for infected patients.

Statement of the desired action(s) to be taken:

Adoption of this revised case definition for chronic HBV infection.

Public Health Impact:

Addition of HBeAg and HBV DNA positive results to the laboratory criteria for diagnosis may increase the number of lab reports received in jurisdictions where these results are not currently reportable. Data from a limited number of sites suggests that the addition of these lab criteria may increase the number of confirmed chronic cases by 30-40%. Addition of the probable case classification category should have no impact of the reporting burden in jurisdictions. The addition of this case classification category will significantly increase the number of cases currently in chronic HBV registries that will meet the case definition (both probable and confirmed) and thus be reported to CDC.

Goals of Surveillance

1. Monitor and describe the burden of disease due to chronic HBV infection.
2. Collect data vital to prevention program planning
3. Provide an opportunity for case management of persons with chronic infection by:
 - a. counseling these persons about ways to reduce transmission to others and prevent further harm to their liver.
 - b. referring chronically infected patients for medical management.
 - c. providing vaccination to household, sexual and needle-sharing contacts.

Methods of Surveillance

Surveillance is conducted using both clinician and laboratory reporting. Core data elements collected by state health departments are reported weekly to the Centers for Disease Control and Prevention through the National Electronic Telecommunications Surveillance System (NETSS) or in the future National Electronic Disease Surveillance System (NEDSS).

Case Definition

Clinical description

Persons with chronic HBV infection may have no evidence of liver disease or may have a spectrum of disease ranging from chronic hepatitis to cirrhosis or liver cancer. Persons with chronic infection may be asymptomatic.

Laboratory criteria for diagnosis

IgM anti-HBc negative AND a positive result on one of the following tests: HBsAg, HBeAg, or HBV DNA

OR

HBsAg positive or HBV DNA positive or HBeAg positive two times at least 6 months apart (Any combination of these tests performed 6 months apart is acceptable.)

Case classification

Confirmed: a case that meets either laboratory criteria for diagnosis

Probable: a case with a single HBsAg positive or HBV DNA positive or HBeAg positive lab result when no IgM anti-HBc results are available

Comment

Multiple laboratory tests indicative of chronic HBV infection may be performed simultaneously on the same patient specimen as part of a “hepatitis panel”. Testing performed in this manner may lead to seemingly discordant results, e.g. HBsAg-negative AND HBV DNA-positive. For the purposes of this case definition, any positive result among the three laboratory tests mentioned above is acceptable, regardless of other testing results. Negative HBeAg results and HBV DNA levels below positive cutoff level do not confirm the absence of HBV infection.

Period of Surveillance

Permanent, with review of reporting needs periodically but at least every five years.

Background and Justification

HBV is a blood borne, sexually and perinatally transmitted virus that causes both acute and, in some cases, chronic infection. The annual estimated number of new HBV infections in the United States has declined from an average of 260,000 in the 1980s to about 73,000 in 2003. The greatest decline in incidence has been observed among children and adolescents as a result of routine infant and childhood hepatitis B vaccination. Based on surveillance data, the highest rate of acute disease currently occurs among persons 20-49-years of age.

Most of the disease burden associated with HBV infection occurs from the sequelae of chronic infection. The likelihood of failing to clear the virus after acute infection and of developing chronic infection is inversely related to the age at which infection occurs. The vast majority of adults (94-98%) with normal immune function will recover from newly acquired HBV infections, eliminate virus from blood, and produce neutralizing antibodies that protect from future infection. However, a substantial proportion of infants (90%), young children (30%) and immunosuppressed persons with acute HBV infection will go on to become chronically infected. Persons with chronic HBV infection are often asymptomatic. However, 15-25% of persons with chronic infection eventually develop cirrhosis or hepatocellular carcinoma. Persons who are chronically infected are often detected through screening programs targeted at blood donors, pregnant women, refugees or persons with risk factors for HBV infection. Chronically infected persons are a major reservoir of transmission to others. Persons who test positive for the presence of HBsAg, HBeAg or HBV DNA are potentially infectious to household, sexual, and needle-sharing contacts.

Many state and local health departments have developed chronic HBV registries in order to monitor the disease burden in their state, develop and/or evaluate prevention programs, and provide educational follow-up and referral for infected patients. National reporting of chronic HBV infection (using the CSTE/CDC case definition) via the National Notifiable Disease Surveillance System (NNDSS) was established by CSTE in 2003. Two changes to the case definition are proposed to improve the completeness of reporting. In order for a person to meet the current case definition for chronic HBV infection, the state or local health department must receive two HBsAg positive test results on the same patient, conducted at least 6 months apart or one positive test and a negative serologic result ruling out acute HBV infection. For many health departments, only a small percentage of reported persons meet either of these criteria, resulting in a potentially significant undercount of chronic HBV cases in their jurisdiction. To improve completeness of reporting, we are proposing that the case definition for chronic HBV infection be revised to allow for reporting of persons with only one positive test indicative of chronic infection as probable cases. Persons who meet the current criteria would be reported as confirmed cases. Second, changes in laboratory testing practices and clinical practice have resulted in an increased volume of testing for HBV DNA and HBeAg. We have incorporated these additional tests into the case definition in order to reflect current practices.

Coordination:

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References:

Division of Viral Hepatitis. Guidelines for Viral Hepatitis Surveillance and Case Management. Centers for Disease Control and Prevention. January 2005.

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