

11-ID-04

Committee: Infectious Disease

Title: Public Health Reporting and National Notification for Chronic Hepatitis B

I. Statement of the Problem:

The chronic hepatitis B case definition is in need of revision to improve the list of disease specific data elements and clarify criteria for case ascertainment.

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

CSTE requests that CDC adopt this standardized reporting definition for chronic hepatitis B.

III. Public Health Impact:

Background and Justification¹

An estimated 1.25 million persons have chronic hepatitis B virus (HBV) infection. Persons with chronic HBV infection are a major reservoir for transmission of HBV infections. Any person testing positive for hepatitis B surface antigen (HBsAg) is potentially infectious to household, sexual and needle-sharing contacts and vaccination should be provided. With widespread screening for HBV infection and the advent of laboratory reporting, an increasing number of persons testing HBsAg-positive are being identified to state health departments. Surveillance data are needed to monitor the disease burden of chronic infection and to develop prevention programs.

IV. Goals of Surveillance

To provide information on the temporal, geographic, and demographic occurrence of chronic hepatitis B to facilitate its prevention and control.

V. Methods for Surveillance:

Surveillance for chronic hepatitis B should use the sources of data and the extent of coverage listed in Table V.

Table V. Recommended sources of data for case identification and extent of coverage for ascertaining cases of chronic hepatitis B.

Source of data for case ascertainment	Coverage	
	Population-wide	Sentinel sites
clinician reporting	X	
laboratory reporting	X	

¹ Much of the material in the background is directly quoted from the CDC's hepatitis B Website. See the References for further information on this source.

reporting by other entities (e.g., hospitals, veterinarians, pharmacies)	X
death certificates	X
hospital discharge or outpatient records	X
extracts from electronic medical records	X
telephone survey	
school-based survey	
other _____	

VI. Criteria for case identification

A. Narrative: A description of criteria for case ascertainment of a specific condition.

Report any illness to public health authorities that meets any of the following criteria:

1. Any person with a positive result for any one of the following three laboratory tests:
 - Hepatitis B surface antigen (HBsAg),
 - Hepatitis B e antigen (HBeAg) or
 - Nucleic acid test for hepatitis B virus DNA (HBV-DNA) (including qualitative, quantitative and genotype testing)
2. A person whose healthcare record contains a diagnosis of chronic hepatitis B.
3. A person whose death certificate lists chronic hepatitis B as a cause of death or a significant condition contributing to death.

Other recommended reporting procedures

- All cases of chronic hepatitis B should be reported.
- Reporting should be ongoing and routine.
- Frequency of reporting should follow the state health department’s routine schedule.

B. Table of criteria to determine whether a case should be reported to public health authorities:

Table VI-B. Table of criteria to determine whether a case should be reported to public health authorities. Requirements for reporting are established under State and Territorial laws and/or regulations and may differ from jurisdiction to jurisdiction. These criteria are suggested as a standard approach to identifying cases of this condition for purposes of reporting, but reporting should follow State and Territorial law/regulation if any conflicts occur between these criteria and those laws/regulations.

Criterion	Reporting
<i>Clinical and Administrative Data</i>	
Healthcare record contains a diagnosis of disease due to chronic hepatitis B	S

Death certificate lists disease due to chronic hepatitis B as a cause of death or a significant condition contributing to death	S
<i>Laboratory Evidence</i>	
Hepatitis B surface antigen (HBsAg) positive	S
Hepatitis B e antigen (HBeAg) positive	S
Nucleic acid test for hepatitis B virus DNA (HBV DNA) positive	S

Notes:

S = This criterion alone is sufficient to report a case

C. Disease Specific Data Elements:

Country of birth

Epidemiological Risk Factors

Did the patient ever:

Have a HBV positive sexual partner

Engage in high risk sexual behavior (MSM, sex worker)

Have contact with a person diagnosed with hepatitis B

Inject or use any non-prescription drugs

Receive blood or blood products

Have long term dialysis

Have a tattoo or body piercing

Jail or prison stay

Have a history of accidental stick or puncture with a sharps contaminated with blood or body fluids

Live in congregate living situation (school, assisted living facility, skilled nursing home, group home)

VII. Case Definition for Case Classification

A. Narrative: Description of criteria to determine how a case should be classified.

Clinical evidence

No symptoms are required. 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.

Laboratory evidence

- IgM antibodies to hepatitis B core antigen (IgM anti-HBc) negative AND a positive result on one of the following tests: hepatitis B surface antigen (HBsAg), hepatitis B e

antigen (HBeAg), or nucleic acid test for hepatitis B virus DNA (including qualitative, quantitative and genotype testing)

OR

- HBsAg positive or nucleic acid test for HBV DNA positive (including qualitative, quantitative and genotype testing) 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 person who meets either of the above laboratory criteria for diagnosis

Probable: a person with a single HBsAg positive or HBV DNA positive (including qualitative, quantitative and genotype testing) or HBeAg positive lab result and does not meet the case definition for acute hepatitis B.

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.

B. Classification Tables:

Table VII-B. Criteria for case classification of chronic hepatitis B.

Criterion	Case Definition		
	Confirmed		Probable
<i>Laboratory Evidence</i>			
Hepatitis B surface antigen (HBsAg) positive	O ¹	O ²	O ¹
Hepatitis B e antigen (HBeAg) positive	O ¹	O ²	O ¹
Nucleic acid test for hepatitis B virus (HBV) DNA positive	O ¹	O ²	O ¹
Hepatitis B core antigen (anti-HBc) IgM negative	N		
Does not meet acute Hepatitis B definition			O

Notes:

N = This criterion in conjunction with all other “N” and any “O” criteria in the same column is required to classify a case.

O = At least one of these “O” criteria in each category in the same column—in conjunction with all other “N” criteria in the same column—is required to classify a case.

Laboratory finding labeled O¹ are a single specimen.

Laboratory findings labeled O² are 2 positive specimens spaced at least 6 months apart. The O² laboratory tests may be used in any combination so long as there is a minimum interval of 6 months between specimens.

VIII. Period of Surveillance

Surveillance should be ongoing.

IX. Data sharing/release and print criteria

- Notification to CDC of confirmed and probable cases of chronic hepatitis B is recommended.
- Chronic HBV infection was made a notifiable condition in 2003 and notification is based on state-mandated reporting of positive serology for HBV by public health laboratories. To date, more than 120,000 reports of chronic HBV infection have been identified to CDC via state health departments. Currently, these reports are summarized annually as aggregate counts by state; however, as state databases for identifying and tracking HBV infected individuals become more well-established and standardized, additional analyses of the infected population by demographic and other characteristics are anticipated.
- Biannual reports back to States from CDC.
- Annual publication of aggregate chronic HBV reports to NNDSS (initiated in 2010) for States providing appropriate approval to CDC.
- There is no current plan to re-release case data. Aggregate reports will be publicly available, and states maintain confidential surveillance databases.

X. References

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4. Council of State and Territorial Epidemiologists (CSTE). Criteria for inclusion of conditions on CSTE nationally notifiable condition list and for categorization as immediately or routinely notifiable. CSTE position statement 08-EC-02. Atlanta: CSTE; June 2008. Available from: <http://www.cste.org>.
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8. Dienstag JL. Chronic Viral Hepatitis. In: Mandell GL, Bennett JE, Dolin R, editors. Principles and Practice of Infectious Diseases, 6th edition. Philadelphia: Churchill Livingstone; 2005.
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XI. Coordination:

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