09-ID-72

Committee: Infectious

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

I. Statement of the Problem

CSTE position statement 07-EC-02 recognized the need to develop an official list of nationally notifiable conditions and a standardized reporting definition for each condition on the official list. The position statement also specified that each definition had to comply with American Health Information Community recommended standards to support "automated case reporting from electronic health records or other clinical care information systems." In July 2008, CSTE identified sixty-eight conditions warranting inclusion on the official list, each of which now requires a standardized reporting definition.

II. Background and Justification

Background[1]

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 are being identified to state health departments. Surveillance data are needed to monitor the disease burden of chronic infection and to develop prevention programs.

Justification

Chronic hepatitis B meets the following criteria for a nationally and **standard** notifiable condition, as specified in CSTE position statement 08-EC-02:

- A majority of state and territorial jurisdictions—or jurisdictions comprising a majority of the US population—have laws or regulations requiring **standard** reporting of chronic hepatitis B to public health authorities
- CDC requests **standard** notification of chronic hepatitis B to federal authorities.
- CDC has condition-specific policies and practices concerning the agency's response to, and use of, notifications.

[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.

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

CSTE requests that CDC adopt this standardized reporting definition for chronic hepatitis B to facilitate more timely, complete, and standardized local and national reporting of this condition.

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 below.

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

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

Reporting refers to the process of healthcare providers or institutions (e.g., clinicians, clinical laboratories, hospitals) submitting basic information to governmental public health agencies about cases of illness that meet certain reporting requirements or criteria. Cases of illness may also be ascertained by the secondary analysis of administrative health data or clinical data. The purpose of this section is to provide those criteria that should be used by humans and machines to determine whether a specific illness should be reported.[2]

[2] "Human-based" criteria (described below under "A. Narrative") can be applied by medical care providers and laboratory staff based on clinical judgment and clinical diagnosis. Machine-based criteria (described below under

A. Narrative description of criteria to determine whether a case should be reported to public health authorities

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 Hepatitis B virus DNA (HBV-DNA), regardless of symptomatology and including asymptomatic persons.
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 on-going 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. Proposed Table of criteria to determine whether a case should be reported to public health authorities. Note: The following criteria are proposed for evaluation before general implementation. For purposes of currently implementing reporting the narrative description in VI-A, should be used.

Criterion	Reporting		
Clinical Presentation			
Asymptomatic	C		
Fatigue	C		
Abdominal fullness	C		
Weight loss	C		
Jaundice	C		
Ascites	C		
Edema	C		
Bruising	C		
GI bleeding	C		

"B. Table") can be applied using computerized algorithms that operate in electronic health record systems, including computerized records of laboratory test orders and laboratory test results; other clinical data systems (e.g., hospital discharge data systems serving multiple hospitals); or administrative data (e.g., healthcare provider billing data, vital records, and EMS data).

Hepatic encephalopathy	C		
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
Laboratory findings			
Hepatitis B surface antigen (HBsAg) positive	O[1]		
Hepatitis B e antigen (HBeAg) positive	O[1]		
Hepatitis B virus (HBV) DNA positive	O[1]		
Hepatitis B core antigen (anti-HBc) IgM negative			
Elevated serum aminotransferases	C		
Elevated alkaline phosphatase	C		
Hyperbilirubinemia	C		
Hypoalbumenemia	C		
Prolonged prothrombin time	C		
Thrombocytopenia	C		
Leukopenia	C		
Histological evidence of chronic hepatitis on liver biopsy	C		
Epidemiological risk factors			
Born outside of US	C		
Mother hepatitis B carrier	C		
IV Drug Use	C		
Sexual contact of hepatitis B carrier Household contact of hepatitis B carrier (non-sexual)	C C		
Multiple sexual partners	C		
MSM	C		
Recipient of multiple transfusions or blood products	C		
Hemodialysis	C		
Medical or dental professional with contact with human blood	C		

Notes:
S = This criterion alone is sufficient to report a case
C = This finding corroborates (i.e., supports) the diagnosis of—or is associated with—Chronic Hepatitis B, but is not included in the case definition and is not required for reporting.

O = At least one of these "O" criteria in each category in the same column (e.g., clinical presentation and laboratory findings)—in conjunction with all other "N" criteria in the same column—is required to classify a case.
Laboratory finding labeled O^1 are a single specimen. Laboratory findings labeled O^2 are 2 positive specimens spaced at least 6 months apart. The O^2 laboratory tests may be used in any combination so long as there is a minimum interval of 6 months between specimens.

C. Disease Specific Data Elements:

Disease-specific data elements to be included in the initial report are listed below.

Born outside of US – indicate country
Mother hepatitis B carrier
IV Drug Use
Sexual contact of hepatitis B carrier
Household contact of hepatitis B carrier (non-sexual)
Multiple sexual partners
MSM
Recipient of multiple transfusions or blood products
Hemodialysis patients
Medical or dental professional with contact with human blood
Residents and staff of facilities for developmentally disable persons

VII. Case Definition for Case Classification

A. Narrative description of criteria to determine whether a case should be classified as confirmed or probable (presumptive) is provided below:

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

B. Classification Tables

Table VII-B lists the criteria that must be met for a case to be classified as confirmed, probable (presumptive), or suspected (possible).

Table VII-B. Proposed table of criteria to determine whether a case is classified. Note: The following criteria are proposed for evaluation before general implementation. For purposes of current notification, the narrative description in VII-A, should be used.

	Case Definition		
Criterion	Confirmed		Probable
Clinical Presentation			
Asymptomatic	C	C	C
Fatigue	C	C	C
Abdominal fullness	C	C	C
Weight loss	C	C	C
Jaundice	C	C	C
Ascites	C	C	C
Edema	C	C	C
Bruising	C	C	C
GI bleeding	C	C	C
Hepatic encephalopathy	C	C	C
Healthcare record contains a diagnosis of disease due to chronic hepatitis B			

Death certificate lists disease due to chronic hepatitis B as a cause of death or a significant condition contributing to death			
Laboratory findings			
Hepatitis B surface antigen (HBsAg) positive	O[1]	O[2]	O[1]
Hepatitis B e antigen (HBeAg) positive	O[1]	O[2]	O[1]
Hepatitis B virus (HBV) DNA positive	O[1]	O[2]	O[1]
Hepatitis B core antigen (anti-HBc) IgM negative	N	A	A
Elevated serum aminotransferases	C	C	C
Elevated alkaline phosphatase	C	C	C
Hyperbilirubinemia	C	C	C
Hypoalbumenemia	C	C	C
Prolonged prothrombin time	C	C	C
Thrombocytopenia	C	C	C
Leukopenia	C	C	C
Histological evidence of chronic hepatitis on liver biopsy	C	C	C
Epidemiological risk factors			
Born outside of US	C	C	C
Mother hepatitis B carrier	C	C	C
IV Drug Use	C	C	C
Sexual contact of hepatitis B carrier Household contact of hepatitis B carrier (non-sexual)	C C	C C	C C
Multiple sexual partners	C	C	C
MSM	C	C	C
Recipient of multiple transfusions or blood products	C	C	C
Hemodialysis	C	C	C
Medical or dental professional with contact with human blood	C	C	C

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 (e.g., clinical presentation and laboratory findings)—in conjunction with all other “N” criteria in the same column—is required to classify a case.

Laboratory finding labeled O^1 are a single specimen. Laboratory findings labeled O^2 are 2 positive specimens spaced at least 6 months apart. The O^2 laboratory tests may be used in any combination so long as there is a minimum interval of 6 months between specimens.
A = This criterion must be absent (i.e., NOT present) for the case to meet the reporting criteria or case definition.
C = This finding corroborates (i.e., supports) the diagnosis of—or is associated with—Chronic Hepatitis B, but is not included in the case definition and is not required for reporting.

VIII. Period of Surveillance

Surveillance should be on-going.

IX. Data sharing/release and print criteria

Notification to CDC for confirmed and probable cases is recommended.

- Chronic HBV infection was made a notifiable condition in 2003 and notification is based on state-mandated reporting of positive tests of antibodies for hepatitis B virus 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.

- Pending evaluation of chronic HBV reports, analyses will be ad-hoc.

- The schedule for analyzing and releasing aggregate chronic HBV reports to NNDSS is in development, pending evaluations of data quality.

- 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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