

Committee: Infectious

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

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

Background¹

An estimated 3.2 million Americans have chronic hepatitis C. Persons with active HCV infection are a major reservoir for transmission of HCV infections. Persons newly infected with HCV are usually asymptomatic, so persons with chronic hepatitis C are usually identified during a routine physical examination because of elevated ALT levels. HCV is transmitted primarily through large or repeated percutaneous exposures to infectious blood, such as injection drug use; receipt of donated blood, blood products, and organs, needlestick injuries in healthcare settings and birth to an HCV-infected mother. HCV can also be spread infrequently through sex with an HCV-infected person, or sharing personal items contaminated with infectious blood. Reporting is particularly needed to identify outbreaks related to invasive medical procedure so that control measures can be implemented and infected persons referred to medical care. States and counties are interested in using these data to monitor the disease burden due to chronic infection and develop prevention and case management programs.

Justification

Hepatitis C 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 hepatitis C to public health authorities
- CDC requests standard notification of hepatitis C 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 C 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 hepatitis C 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 hepatitis C to facilitate its prevention and control.

V. Methods for Surveillance

Surveillance for hepatitis C 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 Hepatitis C.

Source of data for case ascertainment	Coverage	
	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 “B. Table”) can be applied using computerized algorithms that operate in electronic health record systems, including

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. A person with or without symptoms who has tested positive for antibodies to hepatitis C virus (anti-HCV), hepatitis C virus recombinant immunoblot assay (HCV RIBA), nucleic acid test (NAT) for HCV RNA, or HCV genotype.
2. A person whose healthcare record contains a diagnosis of chronic hepatitis C.
3. A person whose death certificate lists chronic hepatitis C as a cause of death or a significant condition contributing to death.

Other recommended reporting procedures

- All cases of hepatitis C 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		
<i>Clinical Presentation</i>			
Acute onset	N	N	
Jaundice	N		
Dark Urine	C		
Malaise	C	O	
Nausea	C	O	
Abdominal Pain	C	O	
Chronic Hepatitis	A	A	
Cirrhosis	A	A	
Carcinoma of the Liver	A	A	

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).

healthcare record contains a diagnosis of Hepatitis C			S
Death certificate lists Hepatitis C as a cause of death or a significant condition contributing to death			S
<i>Laboratory findings</i>			
Elevated serum aminotransferase levels		N	
Antibodies to hepatitis C virus (anti-HCV) screening-test-positive	O	O	
Antibodies to hepatitis C virus (anti-HCV) positive more than 10 weeks prior to current illness			
Hepatitis C Virus Recombinant Immunoblot Assay (HCV RIBA) positive	O	O	
Hepatitis C Virus Recombinant Immunoblot Assay (HCV RIBA) positive more than 10 weeks prior to current illness			
Nucleic Acid Test (NAT) for HCV RNA positive	O	O	
Nucleic Acid Test (NAT) for HCV RNA positive more than 10 weeks prior to current illness			
IgM antibody to hepatitis A virus (IgM anti-HAV) negative	N	N	
IgM antibody to hepatitis B core antigen (IgM anti-HBc) negative	N	N	
<i>Epidemiological risk factors</i>			

Notes:

S = This criterion alone is sufficient to report a case

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

O = At least one of these “O” criteria in each category in the same column (e.g., clinical presentation and laboratory findings) is required to report a case. A number following an “O” indicates that this criterion is only required for a specific clinical presentation

A = This criterion must be absent (i.e., NOT present) for the case to meet the reporting criteria.

C = This finding corroborates (i.e., supports) the diagnosis of—or is associated with—Hepatitis C, but is not required for reporting.

C. Disease Specific Data Elements:

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

Drug user

Sex worker

Vocational exposure to blood body or fluids

Receipt of blood or blood products

Surgery or other medical/dental procedures in last 6 months

VII. Case Definition for Case Classification

A. Narrative description of criteria to determine whether a case should be classified as confirmed:

Clinical case definition

Most HCV-infected persons are asymptomatic; however, many have chronic liver disease, which can range from mild to severe including cirrhosis and live cancer.

Laboratory criteria for diagnosis

One or more of the following three criteria:

1. Anti – HCV positive (repeatedly reactive) by EIA verified by at least one additional more specific assay OR
2. HCV RIBA positive OR
3. Nucleic Acid Test (NAT) for HCV RNA positive OR
4. Report of HCV genotype OR
5. Antibodies to hepatitis C virus (anti-HCV) screening-test-positive with a signal to cut-off ratio predictive of a true positive as determined for the particular assay and posted by CDC. http://www.cdc.gov/ncidod/diseases/hepatitis/c/sc_ratios.htm),

Case classification:

Confirmed: a case that is laboratory confirmed and does not meet the case definition for acute hepatitis C.

Probable: a case that is anti-HCV positive (repeat reactive) by EIA and has alanine aminotransferase (ALT or SGPT) values above the upper limit of normal, but the anti-HCV EIA result has not been verified by an additional more specific assay or the signal to cut-off ratio is unknown.

B. Classification Tables:

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

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	
<i>Clinical Presentation</i>		
Acute onset	N	N
Jaundice	N	

Dark Urine	C	
Malaise	C	O
Nausea	C	O
Abdominal Pain	C	O
Chronic Hepatitis	A	A
Cirrhosis	A	A
Carcinoma of the Liver	A	A
healthcare record contains a diagnosis of Hepatitis C		
Death certificate lists Hepatitis C as a cause of death or a significant condition contributing to death		
<i>Laboratory findings</i>		
Elevated serum aminotransferase levels		N
Antibodies to hepatitis C virus (anti-HCV) screening-test-positive	O	O
Antibodies to hepatitis C virus (anti-HCV) positive more than 10 weeks prior to current illness	A	A
Hepatitis C Virus Recombinant Immunoblot Assay (HCV RIBA) positive	O	O
Hepatitis C Virus Recombinant Immunoblot Assay (HCV RIBA) positive more than 10 weeks prior to current illness	A	A
Nucleic Acid Test (NAT) for HCV RNA positive	O	O
Nucleic Acid Test (NAT) for HCV RNA positive more than 10 weeks prior to current illness	A	A
IgM antibody to hepatitis A virus (IgM anti-HAV) negative	N	N
IgM antibody to hepatitis B core antigen (IgM anti-HBc) negative	N	N
<i>Epidemiological risk factors</i>		

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) is required to classify a case. A number following an “O” indicates that this criterion is only required for a specific clinical presentation

A = This criterion must be absent (i.e., NOT present) for the case to meet the case definition.

C = This finding corroborates (i.e., supports) the diagnosis of—or is associated with—Hepatitis C, but is not included in the case definition.

VIII. Period of Surveillance

Surveillance should be on-going.

IX. Data sharing/release and print criteria

Notification to CDC for confirmed and probable cases of chronic hepatitis C is recommended.

Data sharing/release and print criteria:

- A publication of cases reported from six US sites is planned for 2009. This report includes an estimate of the report rate by site, as well as the basic demographic characteristics of cases reported.
- The schedule for analyzing and releasing aggregate chronic HCV reports to NNDSS is in development, pending evaluations of data quality.
- There is no current plan to re-release case data. Pending evaluations of data quality, aggregate reports are publicly available, and states maintain confidential surveillance databases.

X. References

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