09-ID-40

Committee: Infectious

Title: Public Health Reporting and National Notification for Acute 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

Background[1]

Although only 802 cases of confirmed acute hepatitis C were reported in the United States in 2006, CDC estimates that approximately 19,000 new HCV infections occurred that year, after adjusting for asymptomatic infection and underreporting. Persons newly infected with HCV are usually asymptomatic, so acute hepatitis C is rarely identified or reported. HCV is transmitted primarily through large or repeated percutaneous exposures to infectious blood, such a 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, sharing personal items contaminated with infectious blood. As there is no vaccine available to prevent acute hepatitis C infection, reporting is particularly needed to identify outbreaks related to invasive medical procedure so that control measures can be implemented.

Justification

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

V. Methods for Surveillance

Surveillance for acute hepatitis C should use the sources of data and the extent of coverage listed in table V.

Table V. Recommended sources of data and extent of coverage for ascertaining cases of acute hepatitis C.

	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 "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 who is acutely ill with jaundice and has tested positive for antibodies to hepatitis C virus (anti-HCV), hepatitis C virus recombinant immunoblot assay (HCV RIBA), or nucleic acid test (NAT) for HCV RNA. Associated symptoms may include: dark urine, malaise, anorexia, nausea, and abdominal pain. Tests for IgM antibody to hepatitis B core antigen (anti-HBc) and IgM antibody to hepatitis A virus must both be negative.
2. A person who is acutely ill with elevated serum aminotransferase levels and has tested positive for antibodies to hepatitis C virus (anti-HCV), hepatitis C virus recombinant immunoblot assay (HCV RIBA), or nucleic acid test (NAT) for HCV RNA. Associated symptoms may include: dark urine, malaise, anorexia, nausea, and abdominal pain. Tests for IgM antibody to hepatitis B core antigen (anti-HBc) and IgM antibody to hepatitis A virus must both be negative.
3. A person whose healthcare record contains a diagnosis of acute hepatitis C.
4. A person whose death certificate lists acute hepatitis C as a cause of death or a significant condition contributing to death.

Other recommended reporting procedures

- All cases of acute 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	
Clinical Presentation		
Acute onset	N	N
Jaundice	N	
Dark Urine	C	
Malaise	C	O

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).

Nausea	C	O
Abdominal Pain	C	O
Healthcare record contains a diagnosis of acute hepatitis C		
Death certificate lists acute hepatitis C as a cause of death or a significant condition contributing to death		
Laboratory findings		
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
Epidemiological risk factors		

Notes:
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)—in conjunction with all other “N” criteria in the same column—is required to report a case. A number following an “O” indicates that this criterion is only required for a specific clinical presentation
C = This finding corroborates (i.e., supports) the diagnosis of—or is associated with—Acute 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
Receipt of blood or blood products
    Product
    Date
Blood donor
    Date of last donation
    Date of last donation screened negative for hepatitis C
Surgery or other medical procedures in last 6 months
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

An acute illness with a discrete onset of any sign or symptom consistent with acute viral hepatitis (e.g., anorexia, abdominal discomfort, nausea, vomiting), and either a) jaundice, or b) serum alanine aminotransferase (ALT) levels >400 IU/L.

Laboratory criteria for diagnosis

One or more of the following three criteria:

1. 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 as defined by CDC. (URL for the signal to cut-off ratios: http://www.cdc.gov/ncidod/diseases/hepatitis/c/sc_ratios.htm), **OR**
2. Hepatitis C Virus Recombinant Immunoblot Assay (HCV RIBA) positive, **OR**
3. Nucleic Acid Test (NAT) for HCV RNA positive

AND, meets the following two criteria:

1. IgM antibody to hepatitis A virus (IgM anti-HAV) negative, **AND**
2. IgM antibody to hepatitis B core antigen (IgM anti-HBc) negative

Case classification:

Confirmed: a case that meets the clinical case definition, is laboratory confirmed, and is not known to have chronic hepatitis C.

B. Classification Tables

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

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	
Clinical Presentation		
Acute onset	N	N
Jaundice	N	
Dark Urine	C	
Malaise	C	O
Nausea	C	O
Abdominal Pain	C	O
Healthcare record contains a diagnosis of acute hepatitis C		
Death certificate lists acute hepatitis C as a cause of death or a significant condition contributing to death		
Laboratory findings		
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
Epidemiological risk factors		

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. 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—Acute 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 of confirmed cases of acute hepatitis C is recommended.

- Case reports of acute hepatitis C are analyzed weekly internally, and clusters are confirmed with state health departments. Reports of hepatitis C are summarized annually in the *MMWR*. Also, an extensive analysis of data is conducted for publication annually as a *MMWR Surveillance Summary*, along with case reports of acute hepatitis A and B.

- At minimum, all states receive a quarterly report of cases, as well as the annual MMWR and the MMWR surveillance summary for acute viral hepatitis.

- Publication of data will follow this schedule (at a minimum):
    - Quarterly feedback to state health departments
    - Annually in the MMWR annual report of notifiable diseases.
    - Annually in the MMWR surveillance summary of acute viral hepatitis.

- There is no current plan to re-release case data. Aggregate reports are publicly available, and states maintain confidential surveillance databases.

X. References

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