10-ID-09

Committee: Infectious Disease

Title: Public Health Reporting and National Notification for Hepatitis C Infection, Past or Present

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 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 or poor injection safety practices 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 procedures 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 following recommended 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 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 case identification

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 to determine whether a specific illness should be reported.

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

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), or nucleic acid test (NAT) for HCV RNA (including 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. 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
Clinical Evidence	
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
Laboratory Evidence	
Antibodies to hepatitis C virus (anti-HCV) screening-test-positive	S
Hepatitis C Virus Recombinant Immunoblot Assay (HCV RIBA) positive	S
Nucleic Acid Test (NAT) for HCV RNA positive	S

Notes:
S = This criterion alone is sufficient to report a case

C. Disease Specific Data Elements:

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

Epidemiological Risk Factors
Did the patient ever:
Receive a blood transfusion prior to 1992
Receive an organ or tissue transplant prior to 1992
Receive clotting factor concentrates prior to 1987

Receive long term dialysis
Use non-prescription or "street" drugs
Have direct contact with someone else's blood
Have direct contact with someone diagnosed with hepatitis
Receive a tattoo or body piercing
Receive treatment for a sexually-transmitted infection
Have surgery
Receive injection medications at a doctor's office or as part of a medical procedure

Patient History
The total number of female sex partners
The total number of male sex partners

VII. Case Definition for Case Classification

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

Clinical case definition

No symptoms are required. Most HCV-infected persons are asymptomatic; however, many have chronic liver disease, which can range from mild to severe.

Laboratory criteria for diagnosis

One or more of the following four 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) positive for HCV RNA (including genotype) OR
4. 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. Criteria for case classification for a case of hepatitis C.

	Case Definition		
Criterion	Confirmed		Probable
Laboratory Evidence			
Alanine aminotransferase (ALT or SGPT) values above the upper limit of normal			N
Anti – HCV positive (repeatedly reactive) by EIA	N		N
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		O	
Hepatitis C Virus Recombinant Immunoblot Assay (HCV RIBA) positive	O	O	
Nucleic Acid Test (NAT) for HCV RNA positive	O	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 (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

VIII. Period of Surveillance

Surveillance should be ongoing.

IX. Data sharing/release and print criteria

Data sharing/release and print criteria:

- Notification to CDC of confirmed and probable cases of hepatitis C is recommended.
- A publication of cases reported from six US sites is planned. 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

1. Centers for Disease Control and Prevention (CDC). Case definitions for infectious conditions under public health surveillance. MMWR 1997; 46(No. RR-10):1–57. Available from: http://www.cdc.gov/mmwr/

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7. Council of State and Territorial Epidemiologists, Centers for Disease Control and Prevention. CDC-CSTE Intergovernmental Data Release Guidelines Working Group (DRGWG) Report: CDC-ATSDR Data Release Guidelines and Procedures for Re-release of State-Provided Data. Atlanta: CSTE; 2005. Available from: http://www.cste.org/pdffiles/2005/drgwgreport.pdf or http://www.cdc.gov/od/foia/policies/drgwg.pdf.

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XI. Coordination:

Agencies for Response:

(1) Thomas R. Frieden
Director
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, GA 30333
404-639-7000
txf2@cdc.gov

XII. Submitting Author:

(1) Gary Heseltine MD MPH
Epidemiologist
Texas Dept. State Health Services
Emerging and Infectious Disease Branch, MC 1960
PO Box 149347
Austin, TX 78714-9347
Phone: 512-458-7111 ext. 6352
gary.heseltine@dshs.state.tx.

Co-Authors:

(1) Harry F. Hull, Medical Epidemiologist
HF Hull & Associates, LLC
1140 St. Dennis Court
Saint Paul, MN 55116
(651) 695-8114
hullhf@msn.com

(2) Cecil Lynch, Medical Informaticist
OntoReason
7292 Shady Woods Circle
Midvale, UT 84047
(916) 412.5504
clynch@ontoreason.com

(3) R. Gibson Parrish, Medical Epidemiologist
P.O. Box 197
480 Bayley Hazen Road
Peacham, VT 05862
(802) 592-3357
gib.parrish@gmail.com