Council of State and Territorial Epidemiologists
Position Statement

03-ID-05

Committee: **Infectious Disease**

Title: **Hepatitis C, Acute**

Statement of the Problem:
Acute hepatitis C has been reportable since 1996. This revision of the Hepatitis C, Acute case definition includes alternative criteria for laboratory confirmation of screening-test positive results using signal to cut-off ratios, a method that minimizes the need for additional testing while improving the accuracy of reported test results.

Statement of the desired action(s) to be taken:
CSTE will approve the revised case definition for acute hepatitis C

Goals of Surveillance:
1. Detect outbreaks
2. Monitor trends in incidence and patterns in the risk factors for transmission

Methods for Surveillance:
Clinician and laboratory reporting. Core data elements collected by state health departments and reported weekly to Centers for Disease Control and Prevention through National Electronic Telecommunications Surveillance System (NETSS) or in the future National Electronic Disease Surveillance System (NEDSS).

Case Definition:
Clinical case definition
An acute illness with a) discrete onset of symptoms (such as nausea, vomiting, abdominal pain and diarrhea) and b) jaundice or abnormal serum aminotransferase levels

Laboratory criteria for diagnosis:
Serum alanine aminotransferase levels greater than 7 times the upper limit of normal, and
IgM anti-HAV negative,
and
IgM anti-HBc negative, or if not done, HBsAg negative,
and one of the following:
Antibody to hepatitis C virus (anti-HCV) screening-test-positive verified by an additional more specific assay (e.g. RIBA for anti-HCV or nucleic acid testing for HCV RNA)
OR
Anti-HCV screening-test-positive with a signal to cut-off ratio predictive of a true positive as determined for the particular assay (e.g., $\geq$3.8 for the enzyme immunoassays).

Note for above: New testing platform chemiluminescence immunoassay (VITROS anti-HCV assay) data not available yet to calculate signal to cut-off ratio.

Case classification:
Confirmed: a case that meets the clinical case definition and is laboratory confirmed.

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Period of Surveillance:
Permanent, with review of reporting needs every five years.

Background and Justification:
Surveillance for acute hepatitis C is needed to detect outbreaks and to monitor trends in incidence and patterns in the risk factors for transmission. While acute non-A, non-B hepatitis (most of which was hepatitis C) has been under national surveillance since 1982, acute hepatitis C, specifically, has been under national surveillance since 1996.

Determining the presence of antibody to hepatitis C virus (anti-HCV) is the first step in identifying persons with hepatitis C virus (HCV) infection. Testing for anti-HCV should include use of an antibody screening assay, and for screening-test-positive results, a more specific supplemental assay. Verifying screening-test-positive results for anti-HCV minimizes unnecessary medical visits and psychological harm for individuals who test falsely positive, and ensures that follow-up, counseling, medical referral and evaluation are targeted to patients serologically confirmed as having been infected with HCV. However, substantial variation exists among laboratories in the extent to which they perform reflex supplemental testing and the types of supplemental tests that are used. As a result, an anti-HCV positive laboratory report does not uniformly represent a confirmed positive result. This revision of the case definition includes alternative criteria for laboratory confirmation of screening test positive results using signal to cut-off ratios.

Analysis of early versions of anti-HCV EIA results from volunteer blood donors indicated that average repeatedly reactive signal to cut-off ratios could be used to predict supplemental test-positive results. Additional data from other populations were generated to determine if a specific signal to cut –off ratio could be identified that would predict a true antibody-positive result $\geq$95% of the time, regardless of the anti-HCV prevalence or characteristics of the population being tested. The anti-HCV tests that were evaluated were the two licensed EIAs. On the basis of these evaluations, screening-test-positive average signal to cut-off ratios $\geq$3.8 were highly predictive of supplemental test (RIBA) positivity ($\geq$95%), with limited variability (95%-97%) between groups with different prevalences.
Using the signal to cut-off ratio as an alternative to laboratory confirmation minimizes the need for additional supplemental testing while improving the reliability of reported test results.

Adoption of this case definition will improve public health surveillance by reducing the proportion of case reports that need to be investigated to identify acute cases and limiting follow-up of all anti-HCV positive persons to those who have been serologically confirmed.

References:
CDC. Recommendations for prevention and control of hepatitis C virus (HCV) infection and HCV-related chronic disease. MMWR 1998;47(No. RR-19):1-33).

Division of Viral Hepatitis. Guidelines for Viral Hepatitis Surveillance and Case Management. Centers for Disease Control and Prevention, 2002. Available online at: http://www.cdc.gov/ncidod/diseases/hepatitis/resource/surveillance.htm

CDC. Guidelines for Laboratory Testing and Result Reporting of Antibody to Hepatitis C Virus (Anti-HCV). MMWR 2003; 52 (No. RR-03):1-16. Available online at:http://www.cdc.gov/mmwr/PDF/rr/rr5203.pdf

CSTE position statement case definitions: 2002-ID-01; 2000-ID-7; 1997-ID-10. Available online at: http://www.cste.org/PositionStatementsResolutions.htm

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CDC case definitions: 2000, 1996, 1995, 1990. Available online at: http://www.cdc.gov/epo/dphsi/casedef/case_definitions.htm

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