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To: California Association of Communicable Disease Controllers
California HIV/Sexually Transmitted Diseases (STD) Controllers
Association
California Conference of Local Health Data Managers and Epidemiologists
Other Interested Parties

From: Rachel McLean, M.P.H., Chief, Office of Viral Hepatitis Prevention, STD
Control Branch, California Department of Public Health (CDPH)

Re: Changes to 2020 Hepatitis C Virus (HCV) Surveillance Case Definitions

Date: January 2, 2020

I am writing to inform you of important changes to the U.S. Centers for Disease Control and Prevention (CDC) surveillance case definitions for [acute hepatitis C](#) and [chronic hepatitis C](#), which became effective January 1, 2020. This [case definition revision](#) should begin with cases assigned to surveillance year 2020. CDPH will soon modify related forms and guidelines. In the meantime, here is a summary of the key changes.

1) Age Criteria

All reported acute or chronic hepatitis C cases should be older than 36 months of age. Any positive HCV test result in a child 36 months of age or younger should be investigated as a possible Perinatal Hepatitis C case. A *Confirmed* Perinatal Hepatitis C case is defined as an infant who has a positive test for HCV ribonucleic acid (RNA) nucleic acid amplification test, HCV antigen, or detectable HCV genotype from 2 to 36 months of age (inclusive), and who is not known to have been exposed to HCV via a mechanism other than perinatal.

2) Acute Hepatitis C

The 2020 Acute Hepatitis C Case Definition removes the requirement for the presence of a discrete onset of symptoms for acute cases. Use of bilirubin test results (peak elevated total bilirubin levels 3.0 mg/dL or higher) allow for objective measures of jaundice and can be used in absence of symptoms and/or high peak elevated serum alanine aminotransferase (ALT) levels results.

3) Chronic Hepatitis C, Probable

HCV antibody positive cases with evidence of having cleared their infection (i.e., a known negative HCV RNA test result) at the time of initial report should be considered *Not a Case*. (A person with a positive HCV antibody test result and no or unknown HCV RNA results should still be classified as a *Probable* case.)

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ACUTE Hepatitis C		
2016 Case Definition	2020 Case Definition	Notable Changes
<p>Clinical Criteria</p> <p>An illness with discrete onset of any sign or symptom consistent with acute viral hepatitis (e.g., fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, and abdominal pain),</p> <p>AND</p> <p>(a) jaundice,</p> <p>OR</p> <p>(b) a peak elevated serum alanine aminotransferase (ALT) level >200 IU/L during the period of acute illness.</p>	<p>Clinical Criteria</p> <p>All HCV cases in each classification category should be > 36 months of age, unless known to have been exposed non-perinatally. One or more of the following: Jaundice,</p> <p>OR</p> <p>Peak elevated total bilirubin levels \geq 3.0 mg/dL,</p> <p>OR</p> <p>Peak elevated serum alanine aminotransferase (ALT) levels >200 international units per liter [IU/L],</p> <p>AND</p> <p>The absence of a more likely diagnosis (which may include evidence of acute liver disease due to other causes or advanced liver disease due to pre-existing chronic HCV infection or other causes, e.g., alcohol exposure, other viral hepatitis, hemochromatosis)</p>	<p>Clinical Criteria</p> <ol style="list-style-type: none"> 1) Requirement that all cases be more than 36 months of age 2) Peak elevated total bilirubin levels 3.0 mg/dL or higher enough to meet acute hepatitis C case definition (including in lieu of jaundice symptoms or peak ALT levels over 200 IU/L) 3) Specification that another more likely diagnosis (such as evidence of pre-existing advanced liver disease) should be absent.
<p>Laboratory Criteria for Diagnosis</p> <ul style="list-style-type: none"> • A positive test for antibodies to hepatitis C virus (anti-HCV) • Hepatitis C virus detection test: <ul style="list-style-type: none"> ○ Nucleic acid test (NAT) for HCV RNA positive (including qualitative, quantitative or genotype testing) ○ A positive test indicating presence of hepatitis C viral antigen(s) (HCV antigen)* <p>* When and if a test for HCV antigen(s) is approved by FDA and available.</p>	<p>Laboratory Criteria</p> <p><i>Confirmatory laboratory evidence:</i> Positive HCV detection test: Nucleic acid test (NAT) for HCV RNA positive (including qualitative, quantitative, or genotype testing), OR A positive test indicating presence of hepatitis C viral antigen(s) (HCV antigen)</p> <p><i>Presumptive laboratory evidence:</i> A positive test for antibodies to hepatitis C virus (anti-HCV)</p> <p>Epidemiologic Linkage No epidemiologic linkage is required for case classification.</p>	<p>Laboratory Criteria</p> <p>Distinction between presumptive laboratory evidence (indicated by a positive HCV antibody test) and confirmatory laboratory evidence (indicated by a positive HCV RNA or genotype test).</p>

ACUTE Hepatitis C, Continued		
2016 Case Definition	2020 Case Definition	Notable Changes
<p>Case Classification</p> <p>Probable</p> <ul style="list-style-type: none"> A case that meets clinical criteria and has a positive anti-HCV antibody test, but has no reports of a positive HCV NAT or positive HCV antigen tests, <p>AND</p> <ul style="list-style-type: none"> Does not have test conversion within 12 months or has no report of test conversion. 	<p>Case Classification</p> <p>Probable</p> <ul style="list-style-type: none"> A case that meets clinical criteria and has presumptive laboratory evidence, <p>AND</p> <ul style="list-style-type: none"> Does not have a hepatitis C virus detection test reported, <p>AND</p> <ul style="list-style-type: none"> Has no documentation of anti-HCV or HCV RNA test conversion within 12 months 	<p>Case Classification</p> <p>Probable</p> <p>N/A</p>
<p>Case Classification</p> <p>Confirmed</p> <ul style="list-style-type: none"> A case that meets clinical criteria and has a positive hepatitis C virus detection test (HCV NAT or HCV antigen), <p>OR</p> <ul style="list-style-type: none"> A documented negative HCV antibody, HCV antigen or NAT laboratory test result followed within 12 months by a positive result of any of these tests (test conversion). 	<p>Case Classification</p> <p>Confirmed</p> <ul style="list-style-type: none"> A case that meets clinical criteria and has confirmatory laboratory evidence, <p>OR</p> <ul style="list-style-type: none"> A documented negative HCV antibody followed within 12 months by a positive HCV antibody test (anti-HCV test conversion) in the absence of a more likely diagnosis, <p>OR</p> <ul style="list-style-type: none"> A documented negative HCV antibody OR negative hepatitis C virus detection test (in someone without a prior diagnosis of HCV infection) followed within 12 months by a positive hepatitis C virus detection test (HCV RNA test conversion) in the absence of a more likely diagnosis 	<p>Case Classification</p> <p>Confirmed</p> <p>Clarification that HCV RNA test seroconversion should only be considered an acute HCV case in absence of a prior diagnosis of HCV infection. Note: evidence of HCV reinfection or HCV treatment failure would not be considered acute HCV infection for public health surveillance.)</p>

CHRONIC Hepatitis C		
2016 Case Definition	2020 Case Definition	Notable Changes
<p>Clinical Criteria</p> <p>No available evidence of clinical and relevant laboratory information indicative of acute infection (refer to the criteria for classification Table VII-B in CSTE position statement 15-ID-03). Most hepatitis C virus (HCV)-infected persons are asymptomatic; however, many have chronic liver disease, which can range from mild to severe.</p>	<p>Clinical Criteria</p> <p>All hepatitis C virus cases in each classification category should be more than 36 months of age, unless known to have been exposed non-perinatally. One or more of the following:</p> <p>Jaundice,</p> <p>OR</p> <p>Peak elevated total bilirubin levels ≥ 3.0 mg/dL,</p> <p>OR</p> <p>Peak elevated serum alanine aminotransferase (ALT) levels >200 IU/L,</p> <p>AND</p> <p>The absence of a more likely diagnosis (which may include evidence of acute liver disease due to other causes or advanced liver disease due to pre-existing chronic Hepatitis C virus (HCV) infection or other causes, such as alcohol exposure, other viral hepatitis, hemochromatosis, etc.)</p>	<p>Clinical Criteria</p> <p>N/A; Note: the chronic HCV case definition requires the <i>absence</i> of clinical criteria.</p>
<p>Laboratory Criteria for Diagnosis</p> <ul style="list-style-type: none"> • A positive test for antibodies to hepatitis C virus (anti-HCV) • Hepatitis C virus detection test: <ul style="list-style-type: none"> ○ Nucleic acid test (NAT) for HCV RNA positive (including qualitative, quantitative or genotype testing) ○ A positive test indicating presence of hepatitis C viral antigen(s) (HCV antigen)* 	<p>Laboratory Criteria</p> <p><i>Confirmatory laboratory evidence:</i> Positive HCV detection test: Nucleic acid test (NAT) for HCV RNA positive (including qualitative, quantitative, or genotype testing), OR A positive test indicating presence of hepatitis C viral antigen(s) (HCV antigen)</p> <p><i>Presumptive laboratory evidence:</i> A positive test for antibodies to hepatitis C virus (anti-HCV)</p> <p>Epidemiologic Linkage</p>	<p>Laboratory Criteria</p> <p>Distinction between presumptive laboratory evidence (indicated by a positive HCV antibody test) and confirmatory laboratory evidence (indicated by a positive HCV RNA or genotype test).</p>

* When and if a test for HCV antigen(s) is approved by FDA and available.	No epidemiologic linkage is required for case classification.	
CHRONIC Hepatitis C, Continued		
2016 Case Definition	2020 Case Definition	Notable Changes
<p>Case Classification</p> <p>Probable</p> <ul style="list-style-type: none"> • A case that does not meet clinical criteria or has no report of clinical criteria, <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • Does not have test conversion within 12 months or has no report of test conversion, <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • Has a positive anti-HCV antibody test, but no report of a positive HCV NAT or positive HCV antigen test. 	<p>Case Classification</p> <p>Probable</p> <ul style="list-style-type: none"> • A case that does not meet OR has no report of clinical criteria, <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • Has presumptive laboratory evidence, <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • Has no documentation of anti-HCV or RNA test conversion within 12 months, <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • Does not have an HCV RNA detection test reported. 	<p>Case Classification</p> <p>Probable</p> <p>Clarification that a case with presumptive laboratory evidence (a positive HCV antibody test result) is only considered <i>Probable</i> if there is not a known negative HCV RNA result.</p>
<p>Case Classification</p> <p>Confirmed</p> <ul style="list-style-type: none"> • A case that does not meet clinical criteria or has no report of clinical criteria, <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • Does not have test conversion within 12 months or has no report of test conversion, <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • Has a positive HCV NAT or HCV antigen test. 	<p>Case Classification</p> <p>Confirmed</p> <ul style="list-style-type: none"> • A case that does not meet OR has no report of clinical criteria, <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • Has confirmatory laboratory evidence, <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • Has no documentation of anti-HCV or HCV RNA test conversion within 12 months. 	<p>Case Classification</p> <p>Confirmed</p> <p>N/A</p>