Perinatal Hepatitis C
Local Health Jurisdiction Public Health Investigation Protocol

I. Background

Effective January 1, 2018, the Council of State and Territorial Epidemiologists (CSTE) created a new nationally notifiable condition and public health surveillance case definition for “Hepatitis C, Perinatal,” to capture hepatitis C virus (HCV) infections presumably transmitted from the gestational birth parent to the child immediately before, during, or immediately after childbirth. This protocol provides information from the California Department of Public Health (CDPH) for local health jurisdictions (LHJs) to review hepatitis C-related test results in children 2-36 months of age, classify cases, and conduct related case follow up.

II. Perinatal Hepatitis C Case Investigation Objectives

1. Determine if a suspected case of perinatal hepatitis C meets the criteria for a Confirmed case of Perinatal Hepatitis C according to the 2018 CSTE case definition
2. Report and classify cases in the California Reportable Diseases Information Exchange (CalREDIE) or related local surveillance systems for non-CalREDIE LHJs
3. Identify gestational parents of confirmed perinatal hepatitis C cases
4. Collect information on screening and linkage to care for confirmed perinatal hepatitis C cases
5. Encourage health care providers to provide appropriate follow-up clinical care for perinatal HCV cases and their gestational parents

III. Perinatal Hepatitis C Information

Clinical symptoms
Signs and symptoms of perinatal HCV may range from asymptomatic to fulminant hepatitis. Acute HCV infection can progress to chronic infection. Chronically infected persons are thought to be the main reservoir for new infections.

Modes of transmission
HCV is most often transmitted by percutaneous exposure to blood from a person with hepatitis C infection. Most new hepatitis C infections in the United States are related to sharing injection drug use equipment. Some infections are due to healthcare exposures. Infection via sexual contact or perinatal transmission is possible but uncommon; these modes of transmission are more common in the presence of HIV coinfection. The rate of transmission from gestational parents with hepatitis C infection to their infants is approximately 6 percent; 11 percent if the parent also has HIV coinfection.

Incubation period
Among those who develop symptoms following exposure to HCV, the average period from exposure to symptom onset is 2-12 weeks (range: 2-26 weeks). Most people with chronic HCV infection are asymptomatic and many develop chronic liver disease slowly without any signs or symptoms over decades.

1 “Gestational birth parent” refers to the person who gave birth to the child.
Period of Communicability
An individual is considered infectious anytime HCV ribonucleic acid (RNA) is present in the blood. HCV RNA can be detected in the blood or plasma 1 to 2 weeks after exposure. Approximately 15 to 25 percent of people clear the virus from their bodies without treatment and do not develop chronic infection. The remainder will have HCV RNA and remain infectious unless treated and cured.

HCV Testing Guidelines in Children
HCV antibody testing for children under 18 months of age is not recommended due to transient maternal HCV antibody. Infants with HCV antibody should be tested for HCV RNA to diagnose current infection.

IV. Perinatal HCV Case Definition

2018 CSTE/CDC Confirmed Perinatal Hepatitis C Case Definition:

Infant with a positive test for HCV ribonucleic acid (RNA) test OR

HCV antigen 2 OR
detectable HCV genotype

At ≥2 months and ≤36 months of age AND

Is not known to have been exposed to HCV via a mechanism other than perinatal.

V. Perinatal Hepatitis C Case Reporting and Investigation Protocol (Effective 2018)

1. In CalREDIE, if there is a child who is 2-36 months of age with an Acute or Chronic HCV incident, change the Disease Being Reported (located in the Patient tab) to “Hepatitis C, Perinatal”.
   - If there is a child under two months of age with an Acute or Chronic HCV incident, change the Disease Being Reported to “Hepatitis C, Perinatal” and leave open as “Suspect”. Set up a reminder (e.g. private meeting on Microsoft Outlook that does not include any protected health information) to revisit the case when the child will be two months of age to ask the provider to order HCV RNA testing.

2. For suspected perinatal HCV cases, confirm that the perinatal HCV case definition is met.
   - Review relevant clinical and laboratory information where available.
   - If the child is 2-36 months of age with only HCV antibody positive results (and no known HCV RNA or genotype result), contact the ordering provider to encourage them to order HCV RNA testing. A positive HCV RNA (or genotype) test is needed to meet the case definition.
   - If the child has a positive HCV RNA or genotype result at any point while 2-36 months of age, change the Resolution Status (located in the Case Investigation tab) to “Confirmed.” For children with a positive HCV RNA or genotype result reported during 2-36 months of age

2 When and if a test for HCV antigen(s) is FDA approved and available
followed by a subsequent negative HCV RNA result while still 2-36 months of age, the case should remain Confirmed.

- If the child has a positive HCV antibody result followed by a negative HCV RNA result while 2-36 months of age (with no known positive HCV RNA or genotype), or if the HCV RNA remains unknown, the case classification may remain “Suspect” as a placeholder for future test results.

3. Merge subsequent HCV laboratory test results
   - **Subsequent HCV laboratory test results for an existing perinatal HCV case will not automatically append to that case’s existing perinatal HCV incident.** Thus, new HCV laboratory results will be entered into CalREDIE as a new chronic HCV disease incident. These newly created chronic HCV disease incidents must be manually appended to the perinatal HCV incident.
     
     - E.g. A one month old child received a positive HCV antibody test result. The LHJ changed the child’s chronic HCV disease incident into a perinatal HCV incident and temporarily classified the child as a “Suspect” case. At six months of age, the child was tested for HCV RNA and a positive test result was submitted to CalREDIE via ELR as a new chronic HCV disease incident.
   
   - Use the ARNOLD alert to flag incoming chronic HCV test results for anyone under 3 years of age.
   
   - If new test results come in for a previously reported perinatal hepatitis C case (or one that is under investigation), change the disease incident for the newly reported test results to “Hepatitis C, Perinatal”. Merge the two perinatal HCV incidents. When merging, select the original incident ID, original Patient tab, original Epidemiologic Info tab, and original Contacts tab.

4. Recommended/Optional: Identify the case’s gestational parent.
   - In the CalREDIE “Contacts” tab, click “Add”.
   - In CalREDIE, enter the gestational parent’s identifying information and click “Link Patient” to search for and select an existing CalREDIE profile. Click “OK” and save.
   
   - If the gestational parent does not already have an existing record in CalREDIE, enter their information. Click “OK” and save. **Do not** create a new Disease Incident.

5. Recommended/Optional: Complete the “Epidemiologic Information” tab.
   - Local health jurisdiction communicable disease investigators may choose to complete an OPTIONAL follow-up investigation. If a follow up investigation is conducted, CDPH recommends investigating the items in the “Epidemiologic Information” tab as part of case follow-up.
   
   - For local health jurisdictions that do not use CalREDIE and that choose to conduct a follow up investigation, CDPH recommends downloading and completing the CDPH Perinatal Hepatitis C Case Report Form. The form can be found on the California Department of Public Health website at https://www.cdph.ca.gov/Programs/PSB/Pages/CommunicableDiseaseControl.aspx.

6. Recommended/Optional: Share clinical management recommendations with the child’s and gestational parent’s healthcare provider(s).
   - Hepatitis C direct-acting antiviral (DAA) therapies are not yet approved by the U.S. Food and Drug Administration (FDA) for children under 12 years of age but are being studied.
Children with hepatitis C infection should be routinely monitored for disease progression by a regular healthcare provider who has the capacity to refer patients to a specialist, such as a pediatric hepatologist or gastroenterologist. 

If still infected with hepatitis C at 12 years of age, children should be referred for hepatitis C treatment.

- HCV treatment is not yet FDA approved for people who are pregnant but is being studied.
  - Gestational parents of children with perinatal HCV should receive HCV treatment before becoming pregnant again in order to prevent perinatal transmission of HCV in subsequent pregnancies.

- Other recommendations\(^3\) may include:
  - All children born to a gestational parent with HCV should be tested for HCV infection.
  - Repetitive HCV RNA testing is not recommended.
  - If born to the same gestational parent, the siblings of children with perinatal HCV should be tested for HCV infection.

If it is suspected that a hepatitis C case may be healthcare-associated (i.e., due to failure of a health care institution to adhere to standard precautions), LHJs may contact the CDPH Office of Viral Hepatitis Prevention (OVHP) and the CDPH Healthcare-Associated Infections (HAI) Program. Together, OVHP and the HAI program can help LHJs determine whether and how to proceed with further investigation. OVHP Contact: (510) 620-3400 (main phone line); confidential fax (916) 440-5970. HAI Contact: HAIProgram@cdph.ca.gov.

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