18-ID-07

Committee: Infectious Disease

Title: Public Health Reporting and National Notification for Hepatitis A

☒Check this box if this position statement is an update to an existing standardized surveillance case definition.

I. Statement of the Problem

The hepatitis A case definition is in need of revision to incorporate nucleic acid amplification tests into the laboratory criteria and to improve the list of disease specific data elements and criteria for case ascertainment.

II. Background and Justification

Hepatitis A is a vaccine-preventable, communicable disease of the liver caused by the hepatitis A virus (HAV). It is usually transmitted person-to-person through the fecal-oral route or consumption of contaminated food or water. Hepatitis A is a self-limited disease that does not result in chronic infection. Most adults with hepatitis A have symptoms, including fatigue, low appetite, stomach pain, nausea, and jaundice, that usually resolve within 2 months of infection; most children less than 6 years of age do not have symptoms or have an unrecognized infection.

In 1996, CDC's Advisory Committee on Immunization Practices (ACIP) recommended administration of hepatitis A vaccine to persons at increased risk for the disease, including international travelers, men who have sex with men, non-injection and injection-drug users, and children living in communities with high rates of disease. In 1999, ACIP also recommended routine vaccination for children living in 11 Western states with average hepatitis A rates of >20 cases per 100,000 population and recommended that vaccination be considered for children in an additional six states with rates of 10-20 cases per 100,000 population. ACIP expanded these recommendations in 2006 to include routine vaccination of children in all 50 states. By 2011, the rate of hepatitis A in the United States had fallen to a historic low of 0.4 cases per 100,000 population.

However, since 2011, several large HAV outbreaks have been reported including a multi-state outbreak associated with imported pomegranate arils (2013), an outbreak in Hawaii associated with raw scallops (2016), and a multi-state outbreak associated with frozen strawberries (2016). In 2017, multiple states reported person-to-person HAV outbreaks among people who are homeless or use illicit drugs. In combination, these outbreaks represent the largest person-to-person hepatitis A outbreaks since hepatitis A vaccine was introduced. During these prolonged outbreaks, nucleic acid amplification tests (NAAT) for hepatitis A virus RNA have become more available, warranting recognition as laboratory criteria for diagnosis.

Complete and accurate surveillance data are important for monitoring trends, detecting increases and monitoring spread of HAV. These data can be used retrospectively to assess risks and inform vaccine recommendations.

III. Statement of the desired action(s) to be taken

CSTE recommends the following actions:

1. Utilize standard sources (e.g. reporting*) for case ascertainment for hepatitis A. Surveillance for hepatitis A should use the following recommended sources of data to the extent of coverage presented in Table III.

Table III. Recommended sources of data and extent of coverage for ascertainment of cases of hepatitis A.

Source of data for case ascertainment	Coverage	
	Population-wide	Sentinel sites
Clinician reporting	X	
Laboratory reporting	X	
Reporting by other entities (e.g., hospitals, veterinarians, pharmacies, poison centers), specify:	X	
Death certificates	X	
Hospital discharge or outpatient records	X	
Extracts from electronic medical records	X	
Telephone survey		
School-based survey		
Other, specify:		
		2018 Template

*Reporting: process of a healthcare provider or other entity submitting a report (case information) of a condition under public health surveillance TO local or state public health. Note: notification is addressed in a Nationally Notifiable Conditions Recommendation Statement and is the process of a local or state public health authority submitting a report (case information) of a condition on the *Nationally Notifiable Conditions List* TO CDC.

2. Utilize standardized criteria for case identification and classification (Sections VI and VII and Technical Supplement) for hepatitis A.

3. Please see accompanying NNC Recommendation Statement for additional Desired Actions to be Taken (page 7).

IV. Goals of Surveillance

The main goals of hepatitis A surveillance are to:

- Provide information on the temporal, geographic, and demographic occurrence of hepatitis A
- Detect and provide data to control outbreaks
- Identify contacts of case-patients who require post-exposure prophylaxis
- Characterize changes in the epidemiology of infected populations and risk factors
- Guide vaccination policies and other prevention efforts

V. Methods for Surveillance: Surveillance for hepatitis A should use the recommended sources of data and the extent of coverage listed in Table III.

The majority of hepatitis A cases are identified through laboratory and healthcare provider (e.g., clinicians and hospitals) reporting. Additional cases may also be ascertained from supplemental data sources including death certificates, hospital discharge or outpatient records, and electronic medical records.

VI. Criteria for case ascertainment

A positive hepatitis A test result triggers a laboratory report to public health, which would then conduct a disease investigation to determine whether the individual meets the clinical presentation and/or epidemiologic linkage criteria for case ascertainment. Healthcare providers also report known or suspected cases of hepatitis A infection to the health department, which would also trigger a disease investigation. Hepatitis A cases may also be identified through supplemental data sources including death certificates listing hepatitis A as a cause of death or significant condition contributing to death, or medical records containing a diagnosis of hepatitis A.

A. Narrative: A 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:

Clinical presentation criteria:

- A person who is acutely ill with jaundice. (Associated symptoms or signs might include: fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, abdominal pain, or dark urine.)

Laboratory criteria:

- A person who has tested positive for IgM antibody to hepatitis A (IgM anti-HAV positive) OR
- A person who has tested positive for hepatitis A RNA.

Criteria for epidemiologic linkage:

- A person who is acutely ill with symptoms consistent with acute viral hepatitis and had contact (e.g., household or sexual) with a laboratory-confirmed hepatitis A case 15-50 days prior to onset of symptoms.

Administrative data: A person whose death certificate lists hepatitis A as a cause of death or a significant condition contributing to death.

Clinical data: A person whose healthcare record contains a diagnosis of hepatitis A.

Other recommended reporting procedures

- All cases of hepatitis A should be reported.
- Reporting should be ongoing and routine.
- Frequency of reporting should follow the state health department's routine schedule.

B. Disease-specific data elements to be included in the initial report

Symptoms of viral hepatitis

Serum alanine aminotransferase levels (ALT)

Total bilirubin levels

Immunization History

Number of doses of hepatitis A vaccine received
Date of last dose

Epidemiological Risk Factors
During the 2 to 6 weeks prior to the onset of symptoms did the patient:
Have contact with a person diagnosed with hepatitis A
Household contact (non-sexual)
Sexual contact
Travel outside the country (patient or household contact)
Countries visited
Attend or work in day care setting
Inject or use any "street" drugs
Experienced homelessness

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

Risk Factors for Transmission
In the 2 weeks prior to or the 2 weeks after the patient had onset of symptoms, did the patient work as a food handler or personal caregiver (nurse, patient aide)

VII. Case Definition for Case Classification

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

Clinical Criteria
An acute illness with a discrete onset of any sign or symptom consistent with acute viral hepatitis (e.g., fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, abdominal pain, or dark urine),

AND

a) jaundice or elevated total bilirubin levels ≥3.0 mg/dL, **OR**
b) elevated serum alanine aminotransferase (ALT) levels >200 IU/L,

AND

c) the absence of a more likely diagnosis

Laboratory Criteria
Confirmatory laboratory evidence:

- Immunoglobulin M (IgM) antibody to hepatitis A virus (anti-HAV) positive, **OR**
- Nucleic acid amplification test (NAAT; such as PCR or genotyping) for hepatitis A virus RNA positive

Epidemiologic Linkage
Contact (e.g., household or sexual) with a laboratory-confirmed hepatitis A case 15-50 days prior to onset of symptoms.

Case Classification
Confirmed:

- A case that meets the clinical criteria and is IgM anti-HAV positive[§], **OR**
- A case that has hepatitis A virus RNA detected by NAAT (such as PCR or genotyping) **OR**
- A case that meets the clinical criteria and occurs in a person who had contact (e.g., household or sexual) with a laboratory-confirmed hepatitis A case 15-50 days prior to onset of symptoms.

[§] And not otherwise ruled out by IgM anti-HAV or NAAT for hepatitis A virus testing performed in a public health laboratory.

B. Criteria to distinguish a new case of this disease or condition from reports or notifications which should not be enumerated as a new case for surveillance

Hepatitis A is usually self-limiting and does not result in chronic infection. However, up to 10% of persons with hepatitis A may experience a relapse during the 6 months after acute illnesses. Cases of relapsing hepatitis A should not be enumerated as new cases. In addition, a case should not be counted as a hepatitis A case if there is an alternate, more likely diagnosis.

VIII. Period of Surveillance

Hepatitis A surveillance should be ongoing.

IX. Data sharing/release and print criteria

CSTE recommends the following case statuses be included in the CDC Print Criteria:

- ☒Confirmed
- ☐Probable
- ☐Suspect
- ☐Unknown

X. Revision History

Position Statement ID	Section of Document	Revision Description
11-ID-02	VI-A	EDITED laboratory criteria to include NAAT test and elevated bilirubin levels.
11-ID-02	VI-B	EDITED list of disease-specific data elements to include bilirubin levels.
		DELETED serum aspartate aminotransferase (AST) from disease-specific data elements (non-specific).
11-ID-02	VII-A	EDITED clinical criteria to include elevated bilirubin levels and "in the absence of a more likely diagnosis."
11-ID-02	VII-A	DELETED serum aspartate aminotransferase (AST) from clinical criteria (non-specific).
11-ID-02	VII-A	EDITED clinical criteria to define elevated total bilirubin and ALT levels as >3.0 mg/dL and >200 IU/L, respectively.
11-ID-02	VII-A	EDITED laboratory criteria to include NAAT test.
11-ID-02	VII-A	EDITED case classifications to allow cases that are NAAT positive to be enumerated as confirmed cases. Also revised the original criterion "A case that meets the clinical case definition and is laboratory confirmed" to "A case that meets the clinical criteria and is IgM anti-HAV positive," with a footnote indicating that the IgM anti-HAV positive result should not otherwise be ruled out by IgM anti-HAV or NAAT for hepatitis A virus testing performed in a public health laboratory.
11-ID-02	VII-B	ADDED criteria to distinguish a case of relapsing hepatitis A from a new case.

XI. References

1. Centers for Disease Control and Prevention (CDC). Hepatitis A Questions and Answers for Health Professionals. http://www.cdc.gov/hepatitis/hav/havfaq.htm#vaccine. Accessed March 14, 2018.
2. CDC. Epidemiology and prevention of vaccine-preventable diseases. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C. Public Health Foundation, 2015. Available from: http://www.cdc.gov/vaccines/pubs/pinkbook/index.html.
3. CDC. Chapter 3: Hepatitis A. In: Roush SW, Baldy LM, eds. Manual for the surveillance of vaccine-preventable diseases. Atlanta, GA: CDC; 2018. Available from: http://www.cdc.gov/vaccines/pubs/surv-manual/chpt03-hepa.html.
4. CDC. Prevention of hepatitis A through active or passive immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2006;55(No. RR07):1-23. Available from: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5507a1.htm.

5. CDC. Hepatitis A Outbreaks. http://www.cdc.gov/hepatitis/outbreaks/2017March-HepatitisA.htm. Accessed March 14, 2018.
6. Council of State and Territorial Epidemiologists (CSTE). Public health reporting and national notification for hepatitis A. CSTE position statement 11-ID-02. Atlanta, GA: CSTE; 2011. Available from: http://c.ymcdn.com/sites/www.cste.org/resource/resmgr/PS/11-ID-02.pdf.

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Nationally Notifiable Conditions (NNC) Recommendation Statement

Position Statement Title: Public Health Reporting and National Notification for Hepatitis A

Disease/Condition: Hepatitis A

☒ This statement updates a disease/condition already on the *Nationally Notifiable Conditions List*.
- ☒ No change to the CDC notification timeframe is recommended.
- ☒ No new subtypes or additional disease/condition categories are added to the accompanying position statement.

This NNC Recommendation Statement recommends the following:

1. Utilize standardized criteria for case identification and classification (based on Sections VI and VII and Technical Supplement of accompanying position statement) for hepatitis A and add hepatitis A to the *Nationally Notifiable Condition List*
   - ☐ Immediately notifiable, extremely urgent (within 4 hours)
   - ☐ Immediately notifiable, urgent (within 24 hours)
   - ☒ Routinely notifiable
   - ☐ No longer notifiable

2. CSTE recommends that all States and Territories enact laws (statue or rule/regulation as appropriate) to make this disease or condition reportable in their jurisdiction. Jurisdictions (e.g. States and Territories) conducting surveillance (according to these methods) should submit case notifications* to CDC.

3. Expectations for Message Mapping Guide (MMG) development for a newly notifiable condition: NNDSS is transitioning to HL7-based messages for case notifications; the specifications for these messages are presented in MMGs. When CSTE recommends that a new condition be made nationally notifiable, CDC must obtain OMB PRA approval prior to accepting case notifications for the new condition. Under anticipated timelines, notification using the Generic V2 MMG would support transmission of the basic demographic and epidemiologic information common to all cases and could begin with the new MMWR year following the CSTE annual conference. Input from CDC programs and CSTE would prioritize development of a disease-specific MMG for the new condition among other conditions waiting for MMGs.

4. CDC should publish data on hepatitis A as appropriate (see Section IX of corresponding position statement).

5. CSTE recommends that all jurisdictions (e.g. States or Territories) with legal authority to conduct public health surveillance follow the recommended methods as outlined here and in the accompanying standardized surveillance position statement.

*Notification: process of a local or state public health authority submitting a report (case information) of a condition on the *Nationally Notifiable Conditions List* TO CDC.

Technical Supplement

Table VI. Table of criteria to determine whether a case should be reported to public health authorities.

Criterion	Hepatitis A		
Clinical Evidence			
Acute onset of illness		N	N
Jaundice		N	
Fever			O
Headache			O
Malaise			O
Anorexia			O
Nausea			O
Vomiting			O
Diarrhea			O
Abdominal pain			O
Dark urine			O
Clinical and Administrative Data			
Healthcare record contains a diagnosis of hepatitis A	S		
Death certificate lists hepatitis A as a cause of death or a significant condition contributing to death	S		
Laboratory Evidence			
Hepatitis A IgM positive	S		
Hepatitis A RNA positive	S		
Epidemiological Evidence			
Contact (e.g., household or sexual) with a laboratory-confirmed hepatitis A case 15-50 days prior to onset of symptoms			N
			2018 Template

Notes:
S = This criterion alone is SUFFICIENT to report a case.
N = All "N" criteria in the same column are NECESSARY to report a case.
O = At least one of these "O" (ONE OR MORE) criteria in **each category** (categories=clinical evidence, laboratory evidence, and epidemiological evidence) **in the same column**—in conjunction with all "N" criteria in the same column—is required to report a case.

Table VII. Classification Table: Criteria for defining a case of hepatitis A.

Criterion	Confirmed						
Clinical Evidence							
Acute onset of illness	N	N	N		N	N	N
Jaundice	N				N		
Fever	O	O	O		O	O	O
Headache	O	O	O		O	O	O
Malaise	O	O	O		O	O	O
Anorexia	O	O	O		O	O	O
Nausea	O	O	O		O	O	O
Vomiting	O	O	O		O	O	O
Diarrhea	O	O	O		O	O	O
Abdominal pain	O	O	O		O	O	O
Dark urine	O	O	O		O	O	O
Absence of a more likely diagnosis	N	N	N		N	N	N
Laboratory evidence							
Elevated bilirubin levels, ≥3.0 mg/dL		N				N	
Elevated serum ALT levels >200 IU/L			N				N
Hepatitis A IgM (anti-HAV) positive	N	N	N				
Hepatitis A RNA positive by NAAT				N			
Not otherwise ruled out by IgM anti-HAV or NAAT for hepatitis A virus testing performed in a public health laboratory	N	N	N	N			
Epidemiologic evidence							
Contact (e.g., household or sexual) with a laboratory-confirmed hepatitis A case 15-50 days prior to onset of symptoms					N	N	N
Criteria to distinguish a new case:							
Not counted as a case within the previous 6 months	N	N	N	N	N	N	N
							2018 Template

Notes:

N = All “N” criteria in the same column are NECESSARY to classify a case. A number following an “N” indicates that this criterion is only required for a specific disease/condition subtype (see below). If the absence of a criterion (i.e., criterion NOT present) is required for the case to meet the classification criteria, list the absence of criterion as a necessary component.

O = At least one of these “O” (ONE OR MORE) criteria in **each category** (categories=clinical evidence, laboratory evidence, and epidemiologic evidence) **in the same column**—in conjunction with all “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 disease/condition subtype.