Hepatitis A, Acute

*NOTE-HIGHLIGHTED SECTION HAS BEEN REVISED

IMMEDIATELY REPORTABLE DISEASE

Per NJAC 8:57, healthcare providers and administrators shall immediately report **by telephone** confirmed and suspected cases of acute hepatitis A to the health officer of the jurisdiction where the ill or infected person lives, or if unknown, wherein the diagnosis is made. The health officer (or designee) **must immediately institute the control measures listed below in section 6, "Controlling Further Spread,"** regardless of weekend, holiday, or evening schedules. A directory of local health departments in New Jersey is available at

http://www.state.nj.us/health/lh/directory/lhdselectcounty.shtml

If the health officer is unavailable, the healthcare provider or administrator shall make the report to the Department by telephone to 609.826.5964, between 8:00 A.M. and 5:00 P.M. on non-holiday weekdays or to 609.392.2020 during all other days and hours.

June 2019

1 THE DISEASE AND ITS EPIDEMIOLOGY

A. Etiologic Agent

Hepatitis A is caused by the hepatitis A virus (HAV), a ribonucleic acid (RNA) agent classified as a Picornavirus. There is only one serotype worldwide; it is slow-growing in living cells and resistant to heat, solvents, and acid. Depending on conditions, HAV can be stable in the environment for months. Heating foods at temperatures greater than 185°F (>85°C) for one minute or disinfecting surfaces with a 1:100 dilution of sodium hypochlorite (i.e., household bleach) in tap water is necessary to inactivate HAV.

The major site of viral replication is in the liver. The virus is then excreted in the bile and shed in the stool. It produces either asymptomatic (common in young children) or symptomatic infection ranging from a mild illness to a disabling illness lasting weeks to months.

B. Clinical Description and Laboratory Diagnosis

Hepatitis A is usually characterized by an abrupt onset of fever, fatigue, malaise, anorexia, nausea, and abdominal discomfort; some individuals may experience diarrhea. Jaundice (yellowing of the skin and the whites of the eyes [sclera]), dark urine, and light clay-colored stool may follow a few days later. The likelihood of having symptomatic hepatitis A infection is related to age. In children younger than six years, 70% of infections are asymptomatic. When illness does occur in young children, it is typically not accompanied by jaundice. Among older children and adults, infection typically is symptomatic, with jaundice occurring in more than 70% of patients. Signs and symptoms typically last less than two months, although 10% to 15% of symptomatic persons have prolonged or relapsing infectious disease lasting up to six months. Fulminant hepatitis is rare and can be fatal. The elderly and persons with chronic liver disease are at greater risk of fulminant hepatitis A.

Hepatitis A cannot be differentiated from other types of viral hepatitis on the basis of clinical or epidemiologic features alone and there is no chronic carrier state. Laboratory diagnosis is

based on presence of immunoglobulin M (IgM) antibodies against hepatitis A virus (IgM anti-HAV), an elevated total bilirubin level in conjunction with the presence of jaundice, and/or elevated liver enzymes (i.e., alanine transaminase [ALT or SGPT] and aspartate transaminase [AST or SGOT]).

C. Reservoirs

Humans with active infections (symptomatic or not) are the reservoir for hepatitis A. Rarely, nonhuman primates can serve as a reservoir.

D. Modes of Transmission

In infected persons, HAV replicates in the liver, is excreted in the bile, and is shed in the stool. Thus, the principal mode of transmission is direct or indirect person-to-person spread via the fecal-oral route. Transmission occurs most frequently among close contacts, especially in households and extended family settings. Because the majority of children have asymptomatic or unrecognized infections, they play a key role in hepatitis A viral transmission and can serve as a source of infection for others. HAV transmission is particularly problematic in daycare settings with diapered children in attendance, among sexual contacts of hepatitis A patients, among persons who use illicit drugs, and among travelers to countries where hepatitis A is common, including travel related to international adoption.

Persons become infected by ingesting the virus. This can happen by

- Ingestion of
    - Ready-to-eat or uncooked food (sandwiches, salads, ice cream, strawberries, etc.) that have been contaminated by an infected foodhandler with poor hygiene
    - Undercooked or cooked foods contaminated after cooling, as occurs commonly in outbreaks associated with infected foodhandlers
    - Fecally contaminated drinking water that has been treated inadequately
    - Contaminated produce (such as lettuce or strawberries irrigated or processed with contaminated water)
    - Raw or undercooked shellfish harvested from fecally contaminated waters, OR
- Direct person-to-person contact, including sexual contact (e.g., oral-anal contact).

On rare occasions, HAV has been transmitted by transfusion of blood or blood products collected from donors who were viremic at the time of donation. Since 2002, nucleic acid amplification tests such as polymerase chain reaction (PCR) have been applied to the screening of source plasma used for manufacture of plasma-derived products. Hepatitis A transmission can occur among people using illicit drugs, including injectable and

noninjectable drugs. Crowded living conditions and unsanitary habits associated with illicit drug use are probably responsible for increased hepatitis A rates among this group rather than an activity like needle sharing. Saliva, urine, and nasopharyngeal secretions have not been shown to be a source of infection.

E. Incubation Period

The incubation period for hepatitis A ranges from 15 to 50 days, with an average of 28 to 30 days.

F. Period of Communicability or Infectious Period

Peak infectivity of infected persons occurs during the two-week period before the onset of jaundice or elevated liver enzymes, when concentrations of the virus in stool are the highest. Concentration of virus in stool declines after jaundice appears. The period of infectivity is calculated as two weeks before and one week after the onset of jaundice or elevated liver enzymes. Children can shed HAV for longer periods than do adults, up to ten weeks after onset of clinical illness. Prolonged viral excretion (up to six months) has occasionally been documented in premature infants and those who are severely immunosuppressed. Chronic shedding of hepatitis A in feces does not occur; however, recurrent shedding occurs among persons who have relapsing infectious hepatitis A. Viremia occurs soon after infection and persists through the period of liver enzyme elevation, but at concentrations several orders of magnitude lower than in stool.

Calculating the Period of Infectivity

Onset date of jaundice **OR** elevated liver enzymes _____/_____/_____

Infectivity Period: _____/_____/_____ (Two weeks before onset of jaundice / elevated liver enzymes) **TO** _____/_____/_____ (One week after onset of jaundice / elevated liver enzymes)

G. Epidemiology

Hepatitis A has a worldwide distribution and occurs as sporadic cases, clusters, and outbreaks. In countries where sanitation is poor, infection is common and occurs at an early age. Adults, therefore, are usually thought to be immune. However, as economic conditions continue to improve and positively impact sanitation systems in some endemic countries, the Centers for Disease Control and Prevention (CDC) reports a resurgence of adolescent and adult cases of acute hepatitis A infections.

In the United States, hepatitis A has occurred in large nationwide epidemics approximately every ten year to fifteen years. The national rate of hepatitis has declined steadily since the last peak in 1995, and since 1998 rates have been at historically low levels. The wider use of

vaccine with an estimated 21% increase observed in 2007, has probably contributed to this marked decrease in hepatitis A rates in the United States. In 2007, a total of 2,979 acute clinical cases were reported; the national incidence (1.0 per 100,000 population) was the lowest ever recorded in CDC's surveillance system. After asymptomatic infection and underreporting are taken into account, an estimated 25,000 new infections occurred in 2007.

Historically, national hepatitis A rates have varied by region, age, gender, race, and ethnicity. The highest rates of hepatitis A had been reported in the western region of the United States and observed among adults, men, American Indian/Alaskan Natives (AI/ANs), and Hispanics. However, in 2007, several of the previously observed differences in hepatitis A rates diminished: (a) rates in the West were approximately equal to those in other regions of the United Sates; (b) rates were similar across all age groups, with the highest rates for persons aged 25 to 39 (1.3 per 100,000 population); (c) the overall incidence among males was 1.1 cases per 100,000 population compared with 0.9 cases per 100,000 population among females; (d) the rate for AI/ANs decreased dramatically from more than 60 per 100,000 population to 0.5 cases per 100,000 population and (e) acute HAV infection among persons in close contact with new adoptees from countries of high or intermediate hepatitis A endemicity. In 2007, CDC was notified of a case of fulminant hepatitis A in a nontraveling household contact of an asymptomatic Ethiopian adoptee confirmed to have acute hepatitis A (immunoglobulin M [IgM] antibody to HAV [anti-HAV] positive). This prompted further investigation that led to the identification of 20 other cases of acute hepatitis A among persons with close personal contact to newly arriving internationally adopted children and no history of traveling abroad. Two acute hepatitis A cases were identified among unvaccinated traveling parents. This same study found that 98% of parents traveling to pick up their children had been vaccinated against hepatitis A in accordance with existing Advisory Committee on Immunization Practices (ACIP) recommendations. Since 2007, CDC has received 14 additional reports of acute hepatitis A following exposure to nonjaundiced adoptees arriving from countries of high or intermediate hepatitis A endemicity. In one instance, both adoptive parents developed hepatitis A necessitating hospitalization. In another instance, a 2008 community outbreak with 12 hepatitis A cases associated with an asymptomatic international adoptee; two infected contacts were hospitalized, and acute illness was identified among tertiary contacts in an elementary school.

In 2007, local health departments across New Jersey investigated 342 reports of hepatitis A confirming 119 cases of acute hepatitis A infection. The highest proportion of acute infection was observed among adults aged 18 to 50 years (64%). The next highest population affected was children 6 to 17 years old (18%). The illness was observed in adults aged 51 to 84 years (13%) and children aged 0 to 5 years (05%). Fifty–five percent of the hepatitis A case-patients reported in New Jersey were female. Because of limitations regarding the collection of race and ethnicity data on hepatitis A cases, this information is not presented. Of note, the most frequently identified exposure risk factor for hepatitis A, amongst New Jersey residents, was international travel at 39%—primarily to Central and South America n=25(59%) and Asia n=13(30%). Twenty-nine percent of confirmed cases had an "unknown" source of exposure. Other risk factors and high-risk groups—specifically, close

contact with a confirmed hepatitis A case-patient, men who have sex with men (MSM), and illicit drug use—were associated with 7%, 7%, and 1% of cases, respectively.

H. Treatment

Other than supportive care no therapy is available for hepatitis A.

2 REPORTING CRITERIA AND LABORATORY TESTING SERVICES

A. New Jersey Department of Health (NJDOH) Case Definition

1. Clinical Case Definition

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 >200IU/L,

AND

c) the absence of a more likely diagnosis

2. Laboratory Criteria for Diagnosis

Confirmatory laboratory evidence:

- Immunoglobulin M (IgM) antibody to hepatitis A virus (anti-HAV) positive,

  OR

- Nucleic acid amplification test (NAAT; such as Polymerase Chain Reaction [PCR] or genotyping) for hepatitis A virus RNA positive

Epidemiologic Linkage

Contact (e.g., household or sexual) with a laboratory-confirmed hepatitis A case 2-6 weeks prior to onset of symptoms.

3. 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 2-6 weeks prior to onset of symptoms.

B. Differences from CDC Case Definition

The NJDOH and Centers for Disease Control and Prevention (CDC) case definitions are the same.

3 LABORATORY TESTING AVAILABLE

Hepatitis A cannot be differentiated from other types of viral hepatitis on the basis of clinical or epidemiologic features alone. Appropriate blood tests must be used. Two serologic tests are licensed for the detection of antibodies to HAV:

1. Anti-HAV: Total antibody to HAV. This diagnostic test detects total antibody of both immunoglobulin G (IgG) and IgM subclasses of HAV. Its presence indicates either acute or resolved infection.
    - Total anti-HAV, which appears early in the course of infection, remains detectable for the person's lifetime and provides lifelong protection against disease.
2. IgM anti-HAV: IgM antibody is a subclass of anti-HAV. Its presence indicates a recent infection with HAV (six months or less).
    - Serologic testing to detect IgM antibody to the capsid proteins of HAV (IgM anti-HAV) is required to confirm a diagnosis of acute HAV infection.
    - In most persons, serum IgM anti-HAV becomes detectable five to ten days before the onset of symptoms and lasts about six months after infection.
    - IgM anti-HAV that persists for more than 1 year is thought to be a false-positive result. IgM anti-HAV is rarely detected after recent hepatitis A vaccination.

NOTE: In 2005, state health departments and CDC investigated persons with positive serologic tests for acute HAV infection (i.e., IgM anti-HAV) whose illness was not consistent with the surveillance case definition for acute hepatitis A. Findings indicate that most persons who were tested for IgM anti-HAV that did not have illness consistent with acute viral hepatitis had false-positive test results. Thus, healthcare providers should limit use of IgM anti-HAV testing to persons with evidence of clinical hepatitis or recent exposure to an HAV-infected person. Use of IgM anti-HAV as a screening tool for an asymptomatic person or as part of testing panels for the workup of nonacute liver function abnormalities should be discouraged. For more information, read the *Morbidity and Mortality Weekly Report* article (5/13/05) on this topic at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5418a1.htm.

The Public Health and Environmental Laboratories (PHEL) will accept appropriate specimens for serological testing for the presence of antibody to hepatitis A. PHEL offers two qualitative kit assays: one tests for total antibody (IgM and IgG anti-HAV) and the second tests only for IgM antibody to the virus.

4 PURPOSE OF SURVEILLANCE AND REPORTING AND REPORTING REQUIREMENTS

A. Purpose of Surveillance and Reporting

- To identify outbreaks and potential sources of ongoing transmission, in order to interrupt the chain of transmission
- To identify whether the case-patient may be a source of infection (e.g., a diapered child, daycare attendee, or foodhandler for other persons) and, if so, prevent further transmission
- To identify sources of public health concern (e.g., a salad bar prepared by an infectious foodhandler or identification of a contaminated food source) and to stop transmission from such a source
- To identify exposed persons and ensure timely administration of post-exposure prophylaxis (PEP) or other preventive measures, to prevent further transmission
- To educate case-patients and their contacts about the importance of good personal hygiene
- To educate potentially exposed persons about the signs and symptoms of disease, to facilitate early diagnosis

B. Laboratory Reporting Requirements

The New Jersey Administrative Code (NJAC) 8:57-1.8 requires a laboratory director (or designee) to **immediately report by telephone** positive serology for IgM anti-HAV to the local health officer having jurisdiction over the locality in which the patient lives or, if unknown, to the health officer in whose jurisdiction the healthcare provider requesting the laboratory examination is located.

If the local health officer/department cannot be reached, the report should be made directly and immediately by telephone to the NJDHSS Infectious and Zoonotic Disease Program (IZDP) at 609.826.5964 during business hours or 609.393.2020, after business hours and on weekends and holidays. Such a report shall be followed within 24 hours by a written report electronically submitted over the Internet using the confidential and secure Communicable Disease Reporting Surveillance System (CDRSS). Please refer to the reporting regulations codified at NJAC 8:57 for more information.

C. Healthcare Provider Reporting Requirements

According to NJAC 8:57-1.4, a physician, advanced practice nurse, physician's assistant, or person having control or supervising over a hospital or other healthcare institution **shall immediately report by telephone** a known or suspect case of acute hepatitis A infection to the local health officer having jurisdiction over the locality in which the patient lives or, if unknown, wherein the diagnosis is made.

If the local health officer/department cannot be reached, the report should be made directly and immediately by telephone to NJDHSS IZDP at 609.826.5964 during business hours or 609.393.2020 after business hours and on weekends and holidays. Such a report shall be followed within 24 hours by a written or electronic lab report.

D. Health Officer Reporting and Follow-Up Responsibilities

NJAC 8: 57-1.8 stipulates that a health officer (or designee) who is notified of the existence of a known or suspect case of acute hepatitis A infection **shall immediately report by telephone** to NJDHSS IZDP at 609.826.5964 during business hours or 609.393.2020 after business hours and on weekends and holidays. Such a report shall be followed within 24 hours by a written report electronically submitted over the Internet using the confidential and secure CDRSS. Please refer to the reporting regulations codified at NJAC 8:57 for more information.

5 CASE INVESTIGATION

A. It is the health officer's responsibility to investigate the case by interviewing the patient and others who may be able to provide pertinent information and report the case to NJDHSS using CDRSS. Much of the information required for reporting purposes can be obtained from the case-patient's healthcare provider(s) or the medical record.

1. Collect sufficient laboratory data to classify the case of hepatitis A.

- Verify that the anti-HAV IgM test is positive.
    - Review the lab report or request one if the case was reported by a healthcare provider.
- The presence or absence of jaundice and/or elevated liver enzymes is required to determine if the case represents acute hepatitis A infection.
    - Obtain a total bilirubin lab result from the laboratory if the test was done. Jaundice is usually noticeable when total bilirubin is greater than 2.5mg/dL. In addition, clinical documentation may reflect the presence of jaundice and/or icteric sclera (i.e., the yellowing of the whites of the eyes). Of note, icteric sclera can be readily observed in infants and small children exhibiting jaundice.
    - Alanine transaminase (ALT or SGPT) and aspartate transaminase (AST or SGOT), which are intracellular enzymes, serve as markers of hepatocellular injury. Most ALT is found in the cytosol of the liver. Thus, ALT is the most specific test for recognizing acute and chronic hepatic injury. In many acute liver diseases, such as hepatitis A infection, ALT levels are greater than AST levels.

2. Collect pertinent clinical data for case definition determination and calculating the period of infectivity.

- A case of hepatitis A is most infectious during the two weeks before through one week after the onset of jaundice and/or elevated liver enzymes. Be sure to determine these dates as accurately as possible because PEP is a time-sensitive intervention that is dependent on a contact's level of exposure during the period the case-patient was infectious.
    - Example: If the case-patient first noticed that his/her skin was yellow on October 15, his/her period of infectivity would be October 1 through October 22.
- If no signs or symptoms characteristic of acute hepatitis A (e.g., jaundice, dark urine, or clay-colored stools) are noted, use the collection date of the first specimen that was

positive for elevated liver enzymes (ALT > AST) to determine the patient's infectious period.

- Example: If the case-patient does not report a history of jaundice, dark urine, or clay-colored stools, and the first blood specimen that was positive for elevated liver enzymes (with ALT > AST) was collected on October 18, then the period of infectivity would be October 4 through October 25.

- Anyone exposed to the case-patient during this three-week period should be evaluated to determine if they meet the definition of a "CONTACT" (see Section 6B, part 1).

3. Assess risk to the community.

Determine whether the case-patient participated in foodhandling, patient care, or activities in a supervised care setting during the incubation period for hepatitis A (15 to 50 days prior to illness onset).

- **Foodhandling:** Ask questions to ascertain the case-patient's risk of transmitting the illness via food, patient care (i.e., feeding), etc. Determine whether the case-patient is a foodhandler or patient care provider. If so, appropriate control measures need to be instituted as a single infected foodhandler could transmit hepatitis A to dozens or even hundreds of persons. (See Isolation and Quarantine Requirements in Section 6A below.)

NOTE: A foodhandler is any person who directly prepares, serves, or handles food. Also, a person who administers oral medications to another should be treated in the same way as a foodhandler would be.

- **Supervised care settings:** Hepatitis A is spread through the fecal-oral route. Children with hepatitis A are often asymptomatic; however, they may still be shedding the virus in their stool. Poor hand hygiene among children who wear diapers and the handling and changing of diapers by staff contribute to the spread of the hepatitis A virus. Ask questions to determine whether the case-patient is a child, resident, or employee in a supervised care setting. If so, appropriate control measures need to be instituted. (See Isolation and Quarantine Requirements in Section 6A below.)

4. NOTIFY NJDHSS IZDP IMMEDIATELY IF A SUSPECT CASE-PATIENT ATTENDS OR WORKS IN A SUPERVISED CARE SETTING, WORKS IN A HEALTHCARE FACILITY, WORKS AS A FOODHANDLER, OR PROVIDES PATIENT CARE.

5. Identify potential sources of exposure to prevent further cases.

Identify potential sources of hepatitis A exposure, including the case-patient's exposure to suspect or confirmed cases of hepatitis A during the incubation period (15 to 50 days prior to the case-patient's illness onset). Document all relevant information.

- **Contact with known cases:** Determine a case-patient's knowledge of any possible exposure to an individual with acute hepatitis A and/or individual experiencing similar symptoms as the case-patient. These questions must be asked because hepatitis A can be spread through household and/or sexual contact.

- **Travel:** Ask questions regarding international and domestic travel to identify where the case-patient might have become infected. Persons from developed countries who travel to developing countries are at substantial risk for acquiring hepatitis A. Such persons include tourists, immigrants, and their children returning to their country of origin to visit friends or relatives; persons with travel related to international adoption; military personnel; missionaries; and others who work and study abroad in countries that have high or intermediate endemicity of hepatitis A. National outbreaks of hepatitis A associated with exposure to an infected foodhandler during domestic travel have been documented.
    - Ascertain travel destination(s) and dates of travel.
    - Determine if the case-patient was infectious while traveling.
    - Inquire about travel companions and their health status. If they fit the definition of a contact obtain their names, addresses, telephone number, date of birth, and weight.
    - If warranted, NJDHSS IZDP will issue an interstate notification for PEP and surveillance for
        a. All residents outside New Jersey
        b. New Jersey residents with a temporary out-of-state address
- **International adoption:** Obtain international adoption sponsor agency name and telephone number. In addition, request pre-exposure vaccination status of adopting parents who traveled abroad. CDC reports that data from a study conducted at three adoption clinics in the United States, each screening 100-200 incoming adoptees for hepatitis A each year, indicate that 1-6% of newly arrived international adoptees are acutely infected with HAV (non-jaundiced; IgM antiHAV-positive). A proportion of these adoptees represent a source of infection for susceptible close contacts. The risk for hepatitis A among close personal contacts of international adoptees is estimated at 106 (range:90-819) per 100,000 household contacts of international adoptees within the first 60 days of their arrival in the United States. By comparison, according to surveillance data, the estimated rate of symptomatic hepatitis A in the U.S. general population in 2007 was 1.0 per 100,000 population.
- **Food consumption:** Investigate raw shellfish consumption to determine if acute hepatitis A is associated with ingestion of uncooked or partially cooked shellfish grown in sewage-contaminated waters. A history of foods consumed during the incubation period should be obtained to determine if the case-patient might be a part of a community outbreak resulting from an infected foodhandler or contaminated food product. New Jersey has identified acute illness and family clusters associated with individuals traveling abroad and returning with shellfish they personally imported for their own consumption.
- **Sexual practices:** Hepatitis A outbreaks among MSM have been reported frequently and the Advisory Committee for Immunization Practices (ACIP) has recommended hepatitis A vaccination for this population. The interview should include a sexual practice history throughout the incubation period to determine potential epidemiological links to other cases.

- **Illicit drug use:** In the United States, outbreaks have frequently involved users of injected and noninjected methamphetamine, who have accounted for up to 48% of reported cases during outbreaks. Thus, questions regarding recreational drug use throughout the incubation period should be asked to determine potential epidemiological links to other cases.
- **Unknown source:** CDC reports that approximately 50% of persons with hepatitis A have no source of infection identified and cites one study of adults without an identified source of infection; 52% of these adults lived in households that included a child younger than six years old.

6. **Facilitate the administration of postexposure prophylaxis (PEP) with hepatitis A vaccine and/or immune globulin (IG) to contacts as soon as possible (ASAP) and within 14 days from last exposure to an infectious hepatitis A case-patient.**

7. **NOTIFY NJDHSS IZDP IMMEDIATELY IF CONTACTS ARE ASSOCIATED WITH A HIGH-RISK SETTING.**

B. Entry into CDRSS

The mandatory fields in CDRSS include disease, last name, county, municipality, gender, race, ethnicity, case status, and report status.

The following table can be used as a quick reference guide to determine which CDRSS fields need to be completed for accurate and thorough reporting of hepatitis A cases. The "CDRSS Screen" column includes the tabs that appear along the top of the CDRSS screen. The "Required Information" column provides detailed explanations of what data should be entered.

CDRSS Screen	Required Information
Patient Info	Enter the disease name (hepatitis A), patient demographic information, illness onset date, and the date the case was reported to the local health department (LHD). There are no subgroups for hepatitis A. The patient's primary language, marital status, and household size should also be recorded.
Addresses	Use the additional address fields as needed to record additional addresses (e.g., work address(es), school address(es), or a temporary New Jersey address for an out-of-state case).

CDRSS Screen	Required Information
Clinical Status	Enter clinical information such as past medical history, treatments, medical facility name, dates of emergency department evaluation(s), dates of hospital admission and discharge, treating physician name, mortality status, and known immunizations, especially vaccination(s) against hepatitis.
Signs/Symptoms	The presence of either jaundice or elevated liver enzymes is needed to determine if the case represents acute hepatitis A infection. JAUNDICE: Jaundice is usually noticeable when total bilirubin is greater than 2.5mg/dL. After checking the box that best describes the patient in terms of jaundice (i.e., icteric*, icteric [none], jaundice, or jaundice [none]), enter the total bilirubin level into the Attribute field, which appears next to the checked items(s). * *Icteric* refers to the yellowing of the whites of the eyes (sclera) associated with jaundice. ELEVATED LIVER ENZYMES: Check the box to indicate the presence of elevated liver enzymes, then enter the numeric values for ALT (SGOT) and AST (SGPT) into the Attribute field.
Risk Factors	Check all KNOWN risk factors. If there are not any known risk factors, select "UNKNOWN" AND investigate if the household includes children less than six years old. If yes, check this item as a risk factor and enter the age of the child(ren) into the Attribute field.
Laboratory Eval	Enter the laboratory test name; options include HAV IgM, Total Bilirubin, ALT, and AST. Also, enter the specimen collection date, name of the processing laboratory, ordering healthcare provider, test result (i.e., "POSITIVE/REACTIVE," "NEGATIVE/NONREACTIVE"), and test value.
Contact Tracing	All potentially exposed contacts should be entered under the Contact Tracing tab for local, county, and statewide surveillance efforts. CDRSS requires a "YES" response to one of the two HAV exposure questions before contacts can be added. Contacts can be added individually by selecting the Enter Contact By

CDRSS Screen	Required Information
	Name feature. Each contact record should include the following information: the contact's period of exposure; whether the contact is symptomatic or asymptomatic; his/her demographic information, telephone number(s), marital status, primary spoken language, and exposure risk (options include "CLOSE," "CASUAL," and "UNKNOWN"); and whether the contact used any personal protective equipment. The LHD's response activities, including educating contacts, administering PEP, and verifying if contacts have a history of hepatitis A immunization, should be documented in this section. Select an exposure setting for each contact from among the options that appear in the drop-down menu located to the right of the contact's name. A summary reflecting the total number of contacts identified; each contact's name, age, and relationship to the case-patient; and details regarding exposure should be entered into the Text box located on the contact tracing tab. Also, components of the LHD response, including, but not limited to, the education of contacts, PEP recommendations that were made, how PEP was procured and by whom it was administered, and the extent to which contacts could be followed, should be documented in the Text box located on the contact tracing tab.
Case Comments	Enter general comments (i.e., information that is not discretely captured by a specific topic screen or drop-down menu) in the Comments section. **NOTE:** Select pieces of information entered in the Comments section CANNOT be automatically exported when generating reports. Therefore, whenever possible, record information about the case in the fields that have been designated to capture such data; information included in discrete data fields CAN be automatically exported when generating reports.

CDRSS Screen	Required Information
Epidemiology	Select the route of transmission, method of import (i.e., whether the case was imported and from where [e.g., another county, state, or country]), and the method of case detection. In the Other Control Measures section, choose the "Patient's Role/Function" from the drop-down list (e.g., "DAYCARE PROVIDER," "DAYCARE ATTENDEE," "FOOD HANDLER," or "HEALTHCARE WORKER") and document the location of setting, the last day the case-patient was present at the setting, and the date the case-patient can return to the setting. Enter the NJDHSS-assigned outbreak or investigation number if the case is associated with a recognized outbreak or investigation. In the Comments section, identify the steps taken to prevent transmission to the wider community when the case-patient is associated with high-risk settings.
Case Classification Report Status	Case status options are "REPORT UNDER INVESTIGATION (RUI)," "CONFIRMED," "PROBABLE," "POSSIBLE," and "NOT A CASE." All cases entered by laboratories (including LabCorp electronic submissions) should be assigned a case status of "REPORT UNDER INVESTIGATION (RUI)." Cases still under investigation by the LHD should be assigned a case status of "REPORT UNDER INVESTIGATION (RUI)." Upon completion of the investigation, the LHD should assign a case status on the basis of the case definition. "CONFIRMED," "PROBABLE," and "NOT A CASE" are the only appropriate options for classifying a case of acute hepatitis A (see section 2A). Report status options are "PENDING," "LHD OPEN," "LHD REVIEW," "LHD CLOSED," "DELETE," "REOPENED," "DHSS OPEN," "DHSS REVIEW," and "DHSS APPROVED." Cases reported by laboratories (including LabCorp electronic submissions) should be assigned a report status of "PENDING." Once the LHD begins investigating a case, the report status should be changed to "LHD OPEN." The "LHD REVIEW" option can be used if the LHD has a person who reviews the case before it is closed (e.g., health officer or director

CDRSS Screen	Required Information
	of nursing). Once the LHD investigation is complete and all the data are entered into CDRSS, the LHD should change the report status to "LHD CLOSED." "LHD CLOSED" cases will be reviewed by DHSS and be assigned one of the DHSS-specific report status categories. If additional information is needed on a particular case, the report status will be changed to "REOPENED" and the LHD will be notified by e-mail. Cases that are "DHSS APPROVED" cannot be edited by LHD staff (see Section 5C below). If a case is inappropriately entered (e.g., a case of hepatitis B was erroneously entered as a case of hepatitis A), the case should be assigned a report status of "DELETE." A report status of "DELETE" should NOT be used if a reported case of hepatitis A simply does not meet the case definition. Rather, it should be assigned the appropriate case status, as described above. All cases with a case status other than confirmed require the LHD to select a reason from the "REASON" drop-down menu to support the assigned case status.

*If, after several attempts, the LHD cannot obtain patient information (e.g., the healthcare provider does not return telephone calls), NJDHSS IZDP staff will try to obtain this information on behalf of the LHD—**only** if requested by the health officer (or his/her designee). Use CDRSS to document situations in which a healthcare provider or patient refuses to divulge information that would assist the LHD with implementing an appropriate public health response. The failure of contacts to obtain PEP as recommended by the LHD should be documented in CDRSS as well.*

C. Other Reporting/Investigation Issues

1. Due to potentially serious public health consequences, time constraints associated with PEP, and the logistical challenges that often characterize the public health response to hepatitis A, the LHD is required to enter the case into CDRSS ASAP.

2. Case report forms (e.g., the CDS-1 form) and laboratory reports SHOULD NOT BE mailed to NJDHSS if the requisite information about the case is entered into CDRSS (see Section 5B above).

3. Once the LHD completes its investigation and assigns a report status of "LHD CLOSED," NJDHSS will review the case. NJDHSS will approve the case by changing the report status to "DHSS APPROVED." At this time, the case will be locked for editing

and submitted to CDC. If additional information is received after a case has been placed in "DHSS APPROVED," you will need to contact NJDHSS to reopen the case. This should be done only if the additional information changes the case status of the report.

D. Institution of disease control measures is an integral part of case investigation. It is the local health officer's responsibility to understand and institute the control guidelines listed below in Section 6.

6 CONTROLLING FURTHER SPREAD

A. Isolation and Quarantine Requirements (NJAC 8:57-1.10)

1. Minimum Period of Isolation of Case-Patient

Until afebrile and one week after onset of jaundice. Foodhandlers diagnosed with acute, anicteric hepatitis A infection must be excluded from work for at least 14 days from the onset of any symptoms that are compatible with hepatitis A.

2. Minimum Period of Quarantine of Contacts

Foodhandling contacts:
Twenty-eight days for foodhandling contacts who do not receive PEP within 14 days of their LAST exposure to an infectious hepatitis A case-patient (See Section 6B, part 2 below.)
Quarantine is not necessary for foodhandling contacts who receive PEP within 14 days of their LAST exposure to an infectious hepatitis A case-patient. These foodhandlers may IMMEDIATELY return to work after receiving PEP. **In addition, foodhandlers who can provide documentation reflecting prior hepatitis A vaccination or serologic immunity to hepatitis A virus need not receive PEP nor do they need to be excluded from work.**

NOTE: A foodhandler is any person who directly prepares, serves, or handles food. Also, a person who administers oral medications to another should be treated in the same way as a foodhandler would be. Therefore, the above isolation and quarantine requirements may also apply to persons working outside the food service industry, namely those who are involved in patient, family, health or childcare services.

Prospective childcare setting attendees:
Six weeks for prospective childcare attendees who are asymptomatic and newly laboratory confirmed hepatitis A (i.e., IgM anti-HAV positive). This restriction, for

prospective childcare setting attendees ONLY, is calculated from the HAV positive serum collection date (See Section 6B, part 2 below.)

Sixty days for prospective childcare attendees that are international adoptees younger than 5 years old newly arriving from a country with high or intermediate hepatitis A endemicity, presenting non-jaundice and are laboratory confirmed hepatitis A (i.e., IgM anti-HAV positive). This restriction, for prospective childcare setting attendees ONLY, is calculated from the date of entry into the United States of America and NOT FROM the Hepatitis A positive serum collection date (See Section 6B, part 2 below.)

B. Protection of Contacts

For the purposes of public health interventions, a case-patient is considered infectious for two weeks before through one week after the onset of jaundice or elevated liver enzymes. Fecal shedding of the virus peaks during the week before symptom onset. Control measures include hepatitis A education and the administration of postexposure prophylaxis to contacts (see definition of *contact* directly below) of the case-patient during the case-patient's infectious period. Contacts should be advised to self-monitor for hepatitis A symptoms for 50 days (one full incubation period) and seek medical evaluation if symptoms occur.

1. Identify all potential contacts of the infectious hepatitis A case-patient

- A *contact* is defined as
    - all unvaccinated household members
    - all unvaccinated sexual contacts
    - anyone sharing illicit drugs with the case-patient
    - anyone sharing food or eating or drinking utensils with the case-patient
    - anyone consuming ready-to-eat foods prepared by an infectious foodhandler with diarrhea or poor hygiene
- Identify the name, address, telephone number, date of birth (DOB), weight, and date of last exposure for all household contacts and sexual partners.
- Use the pertinent hepatitis A line list developed by NJDHSS to record the name, address, telephone number, DOB, weight, date of last exposure, and PEP compliance outcomes for all contacts.

NOTE: During the course of an investigation, it might be discovered that a case-patient might have handled food at a social gathering, in a childcare setting, or at a specific venue. Therefore, NJDHSS has developed several setting-specific line list templates to assist LHDs in their response to a case of acute hepatitis A. The titles of these line list templates are as follows: "Sample Line List," "Childcare/School Setting Line List," and "Foodhandler Line List." In addition, the "Hepatitis A Symptom Questionnaire," and "Symptomatic

Close Contact Line List" may be instrumental during an outbreak scenario. These documents are available on the NJDHSS Web site under Hepatitis A Technical Information.

Enter each contact individually into CDRSS to allow for local, county, and statewide surveillance.

2. Recommendations for post-exposure prophylaxis (PEP) with hepatitis A vaccine or immune globulin (IG)

The ability to use hepatitis A vaccine for PEP provides numerous public health advantages, including the induction of active immunity and longer protection, greater ease of administration, higher acceptability and availability, and a cost per dose that is similar to IG. Also, the greater availability and ease of administration of hepatitis A vaccine might increase opportunities to provide PEP to persons at risk for infections.

Previously unvaccinated persons who recently have been exposed to HAV should be administered a single dose of single-antigen vaccine or IG as soon as possible and within 2 weeks from date of last exposure to the confirmed case of acute infection during his/her period of infectivity. Information about the relative efficacy of vaccine compared with IG postexposure is limited, and no data are available for persons older than 40 years or those with underlying medical conditions. Therefore, decisions to use vaccine or IG should take into account patient characteristics associated with more severe manifestations of hepatitis A, including older age and chronic liver disease.

For healthy persons aged 12 months to 40 years, single-antigen hepatitis A vaccine, at the age-appropriate dose as soon as possible and within 2 weeks from date of last exposure to the confirmed case of acute infection during his/her period of infectivity, is preferred to IG because of vaccine advantages that include long-term protection and ease of administration.

For persons older than 40 years, IG is preferred as soon as possible and within 2 weeks from date of last exposure to the confirmed case of acute infection during his/her period of infectivity. IG is preferred because of the absence of information regarding vaccine performance and the more severe manifestations of hepatitis A in this age group; vaccine can be used if IG cannot be obtained. The magnitude of the risk for HAV transmission from the exposure should be considered in decisions to use IG or vaccine. IG should be used for children younger than 12 months old, immunocompromised persons, persons who have had chronic liver disease diagnosed, and persons for whom vaccine is contraindicated.

Persons administered IG for whom hepatitis A vaccine also is recommended for other reasons (i.e., high potential for future exposure to hepatitis A virus) should receive a dose of vaccine simultaneously with IG, as soon as possible and within 2 weeks from date of last exposure to the confirmed case of acute infection during his/her period of infectivity. For persons who receive vaccine, the second dose should be administered according to the

licensed schedule to complete the series. The efficacy of IG or vaccine when administered more than two weeks after exposure has not been established.

NOTE: NJDHSS DOES NOT RECOMMEND SCREENING OF CONTACTS FOR IMMUNITY BEFORE ADMINISTERING PEP. Awaiting the results of serology would delay the administration of PEP, which is most effective in preventing illness when it is given as soon as possible. In addition, there are reports of healthcare providers who failed to administer PEP because they incorrectly interpreted serologic results.

Va

- Two single-antigen inactivated whole-virus hepatitis A vaccines are available: Havrix® (GlaxoSmithKline) and VAQTA® (Merck). To produce each vaccine, cell-culture–adapted virus is propagated in human fibroblasts, purified from cell lysates, inactivated with formalin, and adsorbed to an aluminum hydroxide adjuvant.
- Havrix is prepared with a preservative (2-phenoxyathanol); Vaqta does not contain a preservative.
- Both vaccines are available in pediatric and adult formulations.
- Both vaccines were originally licensed for children age two years and older. On the basis of the results of testing among younger children, the Food and Drug Administration (FDA) approved a reduction to 12 months of age for both vaccines in 2005.

Vaccine Immunogenicity

- Both vaccines are highly immunogenic.
- More than 95% of adults will develop protective antibody within four weeks of a single dose of either vaccine, and nearly 100% will seroconvert after receiving two doses.
- More than 97% of children and adolescents will be seropositive within a month of the first dose. In clinical trials, all recipients had protective levels of antibody after two doses.

Vaccine Efficacy

- Both vaccines are highly effective in preventing clinical hepatitis A.
- The efficacy of Havrix in protecting against clinical hepatitis A was 94% among 40,000 Thai children 1 to 16 years of age who received two doses one month apart while living in villages with high HAV disease rates.
- The efficacy of VAQTA in protecting against clinical hepatitis A was 100% among 1,000 New York children 2 to 16 years of age who received one dose while living in a community with a high HAV disease rate.
- Data concerning the long-term persistence of antibody and immune memory are limited because the current vaccines have been available only since 1995–1996. Estimates of antibody persistence derived from kinetic models of antibody decline indicate that protective levels of anti-HAV could be present for 20 years or longer. Other mechanisms (e.g., cellular) may contribute to long-term protection, but this is unknown.
- The need for booster doses will be determined by postmarketing surveillance studies.

Vaccination Schedule and Use

- Havrix is available in two formulations: pediatric (720 ELISA units [EL.U.] per 0.5-mL dose) and adult (1,440 EL.U. per 1.0-mL dose).
    - Children 1 through 18 years of age should receive a single primary dose of the pediatric formulation followed by a booster dose six to 12 months later.
    - Adults 19 years of age and older receive one dose of the adult formulation followed by a booster six to 12 months later.
    - The vaccine should be administered intramuscularly, using the appropriate injection site and needle size as determined by the patient's age and body mass.

Recommended Doses of Havrix® Hepatitis A Vaccine					
Group	**Age**	**Dose (U)**	**Volume**	**No. Doses**	**Schedule***
Children and Adolescents	1-18 years	720	0.5 mL	2	0, 6-12
Adults	>18 years	1,440	1.0 mL	2	0, 6-12

*Months: 0 months represents timing of the initial dose; subsequent number(s) represent months after the initial dose.

- VAQTA is quantified in units (U) of antigen and is available in pediatric and adult formulations.
    - Children 1 through 18 years of age should receive one dose of pediatric formulation (25 U per dose) with a booster dose six to 18 months later.
    - Adults 19 years of age and older should receive one dose of adult formulation (50 U per dose) with a booster dose six to 18 months after the first dose.
    - The vaccine should be administered intramuscularly, using the appropriate injection site and needle size as determined by the patient's age and body mass.

Recommended Doses of VAQTA® Hepatitis A Vaccine					
Group	**Age**	**Dose (U)**	**Volume**	**No. Doses**	**Schedule***
Children and Adolescents	1-18 years	25	0.5 mL	2	0, 6-18
Adults	>18 years	50	1.0 mL	2	0, 6-18

*Months: 0 months represents timing of the initial dose; subsequent number(s) represent months after the initial dose.

Series Completion

- A number of studies indicate that the two brands of hepatitis A vaccine, Havrix and VAQTA, are interchangeable.
- Booster dose for both vaccines given should be based on the person's age at the time of the booster dose, not the age when the first dose was given.
    - For example, if a person received the first dose of the pediatric formulation of VAQTA at 18 years of age, and returns for the booster dose at age 19 years, the booster dose should be the adult formulation not the pediatric formulation.
    - The minimum interval between the first and booster doses of hepatitis A vaccine is six calendar months.
- If the interval between the first and booster doses of hepatitis A vaccine extends beyond 18 months, it is not necessary to repeat the first dose.

Combination Hepatitis A and Hepatitis B Vaccine

In 2001, the FDA approved a combination hepatitis A and hepatitis B vaccine (Twinrix®, GlaxoSmithKline). Each dose of Twinrix contains 720 EL.U. of hepatitis A vaccine (equivalent to a pediatric dose of Havrix) and 20 mcg of hepatitis B surface antigen protein (equivalent to an adult dose of Engerix-B). The vaccine is administered in a three-dose series at 0, 1, and 6 months. Appropriate spacing of the doses must be maintained to ensure long-term protection from both vaccines. The first and second doses should be separated by at least four weeks, and the second and third doses should be separated by at least five months. Twinrix is approved for persons aged 18 years and older and can be used in persons in this age group with indications for both hepatitis A and hepatitis B vaccines.

In 2007, the FDA approved an alternative schedule for Twinrix with doses at 0, 7, and 21 to 30 days and a booster dose 12 months after the first dose. Because the hepatitis B component of Twinrix is equivalent to a standard dose of hepatitis B vaccine, the schedule is the same whether Twinrix or single-antigen hepatitis B vaccine is used. Single-antigen hepatitis A vaccine may be used to complete a series begun with Twinrix and vice versa. A person 19 years of age or older who receives one dose of Twinrix may complete the hepatitis A series with two doses of adult formulation hepatitis A vaccine separated by at least five months. A person who receives two doses of Twinrix may complete the hepatitis A series with one dose of adult formulation hepatitis A vaccine or Twinrix five months after the second dose. A person who begins the hepatitis A series with single-antigen hepatitis A vaccine may complete the series with two doses of Twinrix or one dose of adult formulation hepatitis A vaccine.

Hepatitis A vaccination is not routinely recommended for healthcare workers, persons attending or working in childcare centers, or persons who work in liquid or solid waste management (e.g., sewer workers or plumbers). These groups have not been shown to be at increased risk for hepatitis A infection. ACIP does not recommend routine hepatitis A vaccination for food service workers, but vaccination may be considered based on local epidemiology.

Prevaccination Serologic Testing

HAV infection produces lifelong immunity to hepatitis A, so there is no benefit in vaccinating someone with serologic evidence of past HAV infection. The risk for adverse events following vaccination of such persons is not higher than the risk for serologically negative populations. As a result, the decision to conduct prevaccination testing should be based chiefly on the prevalence of immunity, the cost of testing and vaccinating (including office visit costs), and the likelihood that testing will interfere with initiating vaccination. Testing of children is not indicated because of their expected low prevalence of infection. Persons for whom prevaccination serologic testing will likely be most cost-effective include adults who were either born in or lived for extensive periods in geographic areas that have a high endemicity of HAV infection (e.g., Central and South America, Africa, Asia); older adolescents and adults in certain populations (i.e., Native Americans, Alaska Natives, and Hispanics); adults in certain groups that have a high prevalence of infection (see above); and adults 40 years of age and older. Commercially available tests for total anti-HAV should be used for prevaccination testing. NJDHSS does not recommend screening of contacts for immunity before administering vaccine PEP (see box on page 18).

Postvaccination Serologic Testing

Postvaccination testing is not indicated because of the high rate of vaccine response among adults and children. Testing methods sufficiently sensitive to detect low anti-HAV concentrations after vaccination are not approved for routine diagnostic use in the United States.

Adverse Reactions Following Vaccination

For both vaccines, the most commonly reported adverse reaction following vaccination is a local reaction at the site of injection. Injection site pain, erythema, or swelling is reported by 20% to 50% of recipients. These symptoms are generally mild and self-limited. Mild systemic complaints (e.g., malaise, fatigue, low-grade fever) are reported by fewer than 10% of recipients. No serious adverse reactions have been reported.

Contraindications and Precautions to Vaccination

Hepatitis A vaccine should not be administered to persons with a history of a severe allergic reaction to a vaccine component or following a prior dose of hepatitis A vaccine, or hypersensitivity to alum or, in the case of Havrix, to the preservative 2-phenoxyethanol. Vaccination of persons with moderate or severe acute illnesses should be deferred until the person’s condition has improved. The safety of hepatitis A vaccination during pregnancy has not been determined; however, because it is an inactivated vaccine, the theoretical risk to the fetus is low. The risk associated with vaccination should be weighed against the risk for HAV infection. Because hepatitis A vaccine is inactivated, no special precautions are needed when vaccinating immunocompromised persons, although response to the vaccine may be suboptimal.

Vaccine Storage and Handling

Hepatitis A vaccine should be stored and shipped at temperatures of 35° to 46°F (2° to 8°C) and should not be frozen.

PEP with Hepatitis A Vaccine (see also Section 8B, part 2):

- Single-antigen hepatitis A vaccine is recommended for previously unvaccinated healthy contacts aged 12 months to 40 years with an age-appropriate dose as soon as possible and within 2 weeks from date of last exposure to the confirmed case of acute infection during his/her period of infectivity.
- A contact aged 12 months or older receiving IG PEP and who is at risk for future exposure to hepatitis A virus should also receive a dose of vaccine simultaneously with the IG, as soon as possible and within 2 weeks from date of last exposure to the confirmed case of acute infection during his/her period of infectivity. The 2006 ACIP hepatitis A vaccination recommendations are located at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5641a3.htm
- Data are not available regarding the performance of Twinrix (double-antigen vaccine used in individuals 18 years or older) for the prevention of hepatitis A following exposure. The concentration of HAV antigen in the vaccine formulation is half that included in the single-antigen vaccine available from the same manufacturer.
- Hepatitis A vaccine resources, to assist LHDs in their response to a case of acute hepatitis A, including consent forms, standing orders and vaccine information statements are available at the NJDHSS Web site under Hepatitis A technical information.

Immune Globulin (IG)

IG Characteristics

IG is a sterilized preparation of concentrated antibodies (i.e., immunoglobulins) made from pooled human blood plasma processed by cold ethanol fractionation. In the United States, only plasma that has tested negative for hepatitis B surface antigen, antibody to human immunodeficiency virus, and antibody to hepatitis C virus (HCV) is used to process IG. In addition, the FDA requires that the process used to produce IG include a viral inactivation step or that final products test negative for HCV-RNA by PCR. Anti-HAV concentrations differ among IG lots and decreasing concentrations have been observed over the preceding 30 years, probably because of the decreasing prevalence of previous HAV infection among plasma donors; however, no clinical or epidemiological evidence of decreased protection has been observed. IG contains no preservatives. Of note, immune globulins are sometimes referred to as gamma globulins or immune serum globulins.

IG Immunogenicity

IG provides protection against HAV infection through passive transfer of antibody. Depending on the IG dosage, protection lasts from three to five months. When administered for PEP, IG confers protection for less than three months.

IG Use and Efficacy

IG PEP should be used, per the manufacturer's package insert, for identified contacts aged younger than 12 months and older than 40 years, contacts that are immunocompromised or have diagnosed chronic liver disease, and contacts for whom hepatitis A vaccine is contraindicated. IG should be administered as soon as feasible after exposure and within 2

weeks from date of last exposure to the confirmed case of acute infection during his/her period of infectivity. IG is 80% to 90% effective in preventing hepatitis A if administered within 14 days of last exposure to the case-patient during his/her infectious period. Efficacy is greater when IG is administered early in the incubation period; when administered later in the incubation period, IG might only attenuate the clinical expression of hepatitis A infection. CDC recommends that IG PEP should ideally be administered within 24 hours of contact identification.

Example:

If a case-patient first noticed that his/her skin was yellow on October 15, his/her period of infectivity would be October 1 through October 22. A household contact who was last exposed to the case-patient on October 17 should receive IG PEP as soon as feasible after being identified as a contact and no later than October 31.

NJDHSS, in accordance with the CDC 2005 guidance documents, does not recommend screening of contacts for immunity before administering IG PEP (see box on page 18). IG resources, to assist LHDs in their response to a case of acute hepatitis A, including consent forms, standing orders and vaccine information statements are available at the NJDHSS Web site under Hepatitis A Technical Information.

How Supplied and Administered

IG is available in 2 milliliter (mL) and 10-mL vials through the distributors listed located on the NJDHSS Web site under Hepatitis A Technical Information. Intramuscular immune globulin (IMIG) is the product used for the prevention of hepatitis A infection. It should be administered according to the package insert. The dose to be administered should be based on the contact's body weight in kilograms (kg). Follow the steps outlined below to determine the appropriate dose of IG that a contact should receive.

1. Convert the contact's weight from pounds (lbs) to kilograms (kg) by dividing the contact's weight in lbs by 2.2. The resulting value is the contact's weight in kg.

2. Determine the actual dose of IG to administer by multiplying the contact's weight in kg (as determined above) by 0.02 mL/kg. The resulting value is the total dose of IG (in mL) that should be administered to the contact.

   Example: For a contact weighing 165 lbs:

   1. Convert the contact's weight from lbs to kg → 165 lbs divided by 2.2 = 75 kg.

   2. Determine the actual dose of IG to administer → 75 kg multiplied by 0.02 mL/kg = 1.5 mL of IG that should be administered to the contact.

Interference with Live Vaccines

IG can interfere with the response of other live vaccines:

- If IG is administered less than two weeks after the administration of measles, mumps, and rubella (MMR) vaccine, the person should be revaccinated with MMR at least three months after IG administration.
- If IG is administered less than three weeks after the administration of varicella vaccine, the person should be revaccinated with varicella vaccine at least five months after IG is administered.
- Alternatively, individuals can speak with their healthcare provider regarding the drawing of MMR and/or varicella titers to determine protective immunity or the need for revaccination.

Adverse Reactions to IG

Local pain and tenderness at the injection site, urticaria, and angioedema may occur. Anaphylactic reactions, although rare, have been reported following the injection of human IG preparations. Anaphylaxis is more likely to occur if IMIG is given intravenously; therefore IG must be administered only intramuscularly, and care should be taken to draw back on the plunger of the syringe before injection in order to be certain that the needle is not in a blood vessel.

IG Storage

IG should be stored at 36° to 46°F (2° to 8°C). Do not freeze. Do not use IG after its expiration date.

C. Managing Special Situations

1. Childcare Setting

A potential for exposure of acute hepatitis A infection in childcare settings exist amongst currently enrolled/employed children and staff, as well as, prospective attendees.

Notification of acute hepatitis A infection amongst attendees and staff

If a confirmed case of hepatitis A occurs in a childcare setting, parents/guardians and staff can be notified using the NJDHSS-approved notification letter. This notification letter describes the signs and symptoms associated with hepatitis A and the prevention and control measures that should be taken. The NJDHSS hepatitis A fact sheet should accompany the letter. These documents are accessible on the NJDSS Web site under Hepatitis A Technical Information.

Control and Prevention Measures

Control of hepatitis A in childcare settings should include the following steps:

1. Reviewing hand hygiene policies with children and staff and ensuring adherence to these policies.

2. Disinfecting objects and environmental surfaces with an appropriate bleach solution. (Household bleach at 1:100 dilution is required to inactivate the hepatitis A virus.)

3. Advising parents/guardians not to transfer their child from a childcare setting where enhanced hepatitis A surveillance is currently ongoing to another childcare setting where enhanced active surveillance is not being performed. (Such transfers might result in missed opportunities to quickly identify new cases of hepatitis A and thereby lead to the further spread of illness.)

4. Instructing parents and staff to notify the childcare program and local health department if any household contacts develop illness compatible with acute hepatitis A.

5. Ensuring that the investigation assesses

- Child population (i.e., age, toilet training status, attendance schedule [days and hours], absenteeism, and potential hepatitis A exposures).
- Staff assignments and responsibilities (i.e., determine if staff members switch or share classrooms or have foodhandling and/or diaper-changing responsibilities).
- Shared space, equipment, and objects as well as no-bake food preparation activities.
- Food preparation (i.e., where, by whom) and any complaints of illness among foodhandlers.

6. PEP should be administered if

- One or more cases of hepatitis A are recognized in childcare attendees or employees.
- Cases are recognized in two or more households of childcare attendees.
- The childcare setting provides care to diapered children. Hepatitis A vaccine or IG PEP, as appropriate, should be administered to all previously unvaccinated staff members and attendees of childcare settings.

NOTE: With respect to childcare settings that do not provide care to children who wear diapers, hepatitis A vaccine or IG, as appropriate, need be administered only to classroom contacts of the case-patient(s).

7. Outbreak Management

- An outbreak is defined as hepatitis A cases in three or more families or persons affiliated with the childcare setting.
- Hepatitis A vaccine or IG is recommended for household contacts of a diapered child enrolled in the childcare setting.
- If a household member has confirmed hepatitis A, the child or staff member living there should get a blood test to see if he/she is acutely infected.

  - If the test is negative, he/she should receive PEP IG.
  - If the test is positive for anti-HAV IgM, exclude as for symptomatic children or staff (below).
- Exclusion Guidelines
  - Exclude symptomatic children or staff.
  - Exclude people within two weeks of their last exposure to hepatitis A, unless (a) they receive a prophylactic dose of IG within 14 days of exposure, (b) provide proof of vaccination, or (c) prove immunity through serology.
- Returning after exclusion
  - People excluded can return to the childcare program/center six weeks after the last case is identified.
  - People with acute hepatitis A can return to the program no less than one week after illness onset, provided their fever and jaundice are gone.

Prospective childcare setting attendees

Local health departments will restrict, for **six weeks**, asymptomatic prospective attendees (children) that are newly laboratory confirmed hepatitis A (i.e., IgM anti-HAV positive) from attending a childcare program. This restriction, **for prospective childcare setting attendees ONLY,** is calculated from the HAV positive serum collection date.

Local health departments will restrict, for **sixty days**, prospective attendees (children) that are international adoptees younger than 5 years old newly arriving from a country with high or intermediate hepatitis A endemicity, presenting non-jaundice and are laboratory confirmed hepatitis A (i.e., IgM anti-HAV positive). This restriction, **for prospective childcare setting attendees ONLY,** is calculated from the date of entry into the United States of America and NOT FROM the Hepatitis A positive serum collection date.

2. Close Contacts of Newly Arriving International Adoptees

In 2009, ACIP updated its guidance by recommending hepatitis A vaccination for all previously unvaccinated persons with close personal contact (e.g., household contact or regular babysitting) to an international adoptee from a country of high or intermediate endemicity **during the first 60 days following arrival of the adoptee in the United States**.

3. Community Residential Programs and Long-Term Care Facilities

Actions taken in response to a case of HAV in a community residential program or long-term care facility are handled on a case-by-case basis. Management of contacts will depend on the level of hygiene of the case-patient and the type of facility. Roommates and anyone sharing food or eating or drinking utensils should be considered household contacts and should be given hepatitis A vaccine or IG PEP within 14 days of last exposure. If hepatitis A occurs in

a staff member of a residential program or long-term care facility, a determination should be made regarding whether the staff member is a foodhandler. Staff should be considered an infectious foodhandler if there was an opportunity to feed, distribute medication, prepare foods, or perform dental procedures during the two weeks prior to onset of jaundice or elevated liver enzymes. In such a circumstance, consult with NJDHSS IZDP.

4. Food Service Establishments and Foodhandlers

A confirmed case of hepatitis A in a foodhandler is a potentially serious event and requires that risk of HAV infection for both coworkers and the public be assessed as quickly as possible.

1. If a foodhandler has laboratory-confirmed hepatitis A,

- All other foodhandling employees must receive hepatitis A vaccine or IG PEP within two weeks of last exposure to the foodhandler. If not, they should be excluded from work for **28 days from the date of their last exposure to the foodhandler.** The same exclusion criteria apply to any foodhandling contacts of any confirmed case. (See Section 6A above.)
- A sample Work Exclusion Notification Form is available on the NJDHSS Web site under Hepatitis A Technical Information.
- A foodhandling coworker may return immediately to work upon receiving PEP.
- Work exclusion exception:
    - The foodhandler contacts can produce documentation of at least one dose of hepatitis A vaccination administered more than four weeks prior to exposure to the index case.
    - The foodhandler contacts provide serologic proof of hepatitis A immunity.

2. To determine if the public needs to be notified of possible hepatitis A exposure, a foodhandling history for the two weeks prior to symptom onset must be completed. This review must include the foodhandler's work dates, job duties, foods prepared, and whether gloves or other barrier protection were used by the foodhandler.

3. Consult with NJDHSS IZDP to ensure that a coordinated public health response occurs and statewide surveillance for cases crossing municipal and county jurisdictions is performed.

4. In most instances, transmission of hepatitis A from a common source to patrons is unusual. Therefore, administration of PEP to patrons is usually not recommended. However, PEP to patrons is indicated if

- During the time when the foodhandler was likely to be infectious, the foodhandler BOTH directly handled foods (i.e., served uncooked or foods after cooking) AND had diarrhea or poor hygienic practices

  AND

- Patrons can be identified, recruited, and treated with hepatitis A vaccine or IG PEP within two weeks after the exposure.

5. In settings where repeated exposures to hepatitis might have occurred (e.g., institutional cafeterias) stronger consideration of more widespread PEP use might be warranted. In such instances, consultation with staff in NJDHSS IZDP is warranted.

6. In the event of a common-source outbreak, PEP should not be provided to exposed persons if cases have begun to occur two weeks after the most recent hepatitis A exposure. IG or hepatitis A vaccine is most effective if given within two weeks of hepatitis A exposure, and is believed to be of little benefit thereafter.

5. Schools, Hospitals, and Work Settings

Hepatitis A PEP is not routinely indicated when a single case occurs in an elementary or secondary school or an office or other work setting and the source of infection is outside the school or work setting. Similarly, when a person who has hepatitis A is admitted to a hospital, staff members should not routinely be administered PEP; instead, careful hygienic practices should be emphasized. Hepatitis A vaccine or IG PEP should be administered to persons who have close contact with case-patients if an epidemiologic investigation indicates HAV transmission has occurred among students in a school or among patients or between patients and staff members in a hospital. Furthermore, if a hospital staff member is diagnosed with hepatitis A and is considered a foodhandler, then the isolation requirements for foodhandlers must be followed. (See Section 6A.)

6. Kindergarten or Preschool

If a case of hepatitis A occurs in a kindergarten or preschool class, or a class where hygiene may not be optimal, more stringent control measures may be needed. Please refer to the section on childcare setting above.

1. Strictly enforce hand-washing and cleanliness policies and ensure that all bathrooms are properly supplied with soap, paper towels, and toilet paper.

2. Investigate classroom activities to determine if there might be opportunities for fecal-oral transmission of HAV through activities such as, but not limited to, no-bake cooking or cupcake decorating.

3. Consider notifying parents/guardians and staff of the case using the NJDHSS-approved notification letter. This notification letter describes the signs and symptoms associated with hepatitis A and the prevention and control measures that should be taken. The NJDHSS hepatitis A fact sheet should accompany the letter. These documents are located on the NJDSS Web site under Hepatitis A Technical Information.

4. Request that all parents and staff notify the school if any person in their household is diagnosed with hepatitis A.

7. Workers Exposed to Sewage

In three published reports of serologic surveys conducted among U.S. wastewater workers and appropriate comparison populations, no substantial or consistent increase in prevalence of anti-HAV was identified among wastewater workers. No work-related instances of hepatitis A transmission have been reported among wastewater workers in the United States.

7 OUTBREAK SITUATION

A. Reported Incidence Is Higher Than Usual/Outbreak Suspected

If the number of reported cases of hepatitis A in a city/town is higher than usual, or if an outbreak is suspected, investigate cases clustered in an area or institution to determine the source of infection and mode of transmission. The potential of a common vehicle (such as food or association with a childcare setting) must be investigated and applicable preventive or control measures instituted. Control of person-to-person transmission requires special emphasis on personal cleanliness and sanitary disposal of feces. In all instances of a suspected outbreak, consult with NJDHSS IZDP. IZDP subject matter experts can assist with determining a course of action to prevent further spread of illness. In addition, IZDP staff can perform statewide surveillance for hepatitis A cases that may cross several jurisdictions and therefore be difficult to identify at the local level.

8 PREVENTIVE MEASURES

A. Personal Preventive Measures/Education

In general, individuals can avoid exposure to the virus through

1. Practicing good hand hygiene:

- Washing hands thoroughly with soap and water, especially before handling or eating food, after toilet use, and after changing diapers. Meticulous hand hygiene is the single most important protective measure.
- Childcare providers should wash their own as well as the child’s hands after diaper changing, and dispose of feces in a sanitary manner.
- Persons should also wash their hands thoroughly and frequently when ill with diarrhea, or when caring for someone with diarrhea. Hands should be washed for at least 15 to 20 seconds with soap and water, after using the toilet or helping someone use the toilet, after changing diapers, before handling food, and before eating.

2. Getting vaccinated:

According to the 2006 and 2009 ACIP recommendations, routine vaccination is indicated for

- Children aged 1 year through 18 years.
- Persons who are at increased risk for infection:
    - Persons (one year of age or older) traveling to or working in countries with high or intermediate rates of hepatitis A, such as Central or South America, the Caribbean, Mexico, Asia (except Japan), Africa, and southern or eastern Europe. (See Section 8B for more information about use of hepatitis A vaccine in international travelers.)
    - Persons (one year of age or older) who anticipate close personal contact (e.g., household contact or regular babysitting) with an international adoptee from a country of high or intermediate endemicity
    - MSM
    - Illegal drug users (injectable or noninjectable drugs)
    - Persons with chronic liver disease, including those who are awaiting or have received liver transplants
    - Persons who receive clotting factor concentrates
    - Persons who have occupational risk for infection; specifically, those who work with HAV-infected primates or with HAV in a research laboratory setting. However, sewage workers do not need to be vaccinated.
- Any person wishing to obtain immunity

3. Avoiding consumption of potentially contaminated food:

- Boiling or cooking food and beverage items for at least one minute at 185ºF inactivates the virus.

4. Avoid sexual practices that may permit fecal-oral transmission:

- Use of latex barrier protection (e.g., dental dam) may prevent hepatitis A transmission to sexual partners as well as prevent exposure to and transmission of other pathogens.

5. Disposing of feces in a sanitary manner.

NOTE: According to 2006 ACIP recommendations, all children ages 1 through 18 years should receive hepatitis A vaccination. Current incidence of hepatitis A in New Jersey communities does not warrant mandatory childhood vaccination. If a major outbreak occurs in a community or larger area, NJDHSS

may determine, based on local epidemiologic data and ACIP guidelines, that mass vaccination of certain groups is warranted.

B. Recommendations for Pre-exposure Protection against Hepatitis A for Travelers

All susceptible persons traveling to or working in countries that have high or intermediate hepatitis A endemicity are at increased risk for HAV infection and should be vaccinated or receive IG before departure.

1. **Data are not available regarding the risk for hepatitis A for persons traveling to certain areas of the Caribbean, although prophylaxis should be considered if travel to areas with questionable sanitation is anticipated.**

2. **Travelers to Australia, Canada, western Europe, Japan, or New Zealand (i.e., countries in which endemicity is low) are at no greater risk for infection than are persons living or traveling in the United States.**

3. **Hepatitis A vaccination at the age-appropriate dose is preferred to IG.**

- The first dose of hepatitis A vaccine should be administered as soon as travel is considered or international adoption is planned.
- Ideally unvaccinated persons who anticipate close personal contact (e.g.,household contact or regular babysitting) with an international adoptee from a country of high or intermediate endemicity, should receive the first dose of hepatitis vaccine 2 or more weeks before the arrival of the adoptee.
- Based on limited data indicating equivalent postexposure efficacy of IG and vaccine among healthy persons aged 40 years or younger, one dose of single-antigen hepatitis A vaccine administered at any time before departure can provide adequate protection for most healthy persons.
- Completion of the vaccine series according to the licensed schedule is necessary for long-term protection.
- No data are available for other populations or other hepatitis A vaccine formulations (e.g.,Twinrix®)

4. **Pre-exposure travel prophylaxis with IG can be used for**

- Children aged younger than 12 months (because vaccine is not licensed for use in this age group)
- Persons allergic to a component of the vaccine
- Persons who elect not to receive vaccine

NOTE: A single dose of IG (0.2mL/kg) provides effective protection against hepatitis A for up to three months.

IG can interfere with the response of other live vaccines:
i) MMR should be delayed for at least three months after receiving IG
ii) Varicella vaccine should be delayed for at least five months after receiving IG

5. Hepatitis A vaccine can also be used as pre-exposure travel prophylaxis in conjunction with IG:

- All susceptible persons traveling to or working in countries that have high or intermediate hepatitis A endemicity should be vaccinated or receive IG before departure (See Table). Hepatitis A vaccine at the age-appropriate dose is preferred to IG. The first dose of hepatitis A vaccine should be administered as soon as travel is considered. One dose of single-antigen hepatitis A vaccine administered at any time before departure can provide adequate protection for most healthy persons.
- Older adults, immunocompromised persons, and persons with chronic liver disease or other chronic medical conditions planning to depart to an area within two weeks should receive the initial dose of vaccine and also simultaneously can be administered IG (0.02 mL/kg) at a separate anatomic injection site.
- Travelers who elect not to receive vaccine, or are younger than 12 months old, or are allergic to a vaccine component should receive a single dose of IG (0.02 mL/kg), which provides effective protection for up to 3 months. Those who do not receive vaccination and plan to travel for longer than 3 months should receive an IG dose of 0.06 mL/kg, which must be repeated if the duration of travel is longer than five months.

Hepatitis A Recommended Pre-exposure Travel Prophylaxis		
Duration of Exposure	**Hepatitis A Vaccine**	**Substitute with IG if vaccine is contraindicated or refused**
Short term < 3 months	YES	IG 0.02 mL/kg
3–5 months	YES	IG 0.06 mL/kg
> 5 months	YES	IG 0.6 mL/kg every 5 months

6. In addition, travelers should pay attention to what they eat and drink. Taking precautions such as those listed below will help prevent other illnesses as well, including travelers' diarrhea, cholera, dysentery, and typhoid fever. Recommendations to travelers include

- "Boil it, cook it, peel it, or forget it."
- Drink only bottled or boiled water, keeping in mind that bottled carbonated water is safer than uncarbonated water.
- Ask for drinks without ice unless the ice is made from bottled or boiled water.
- Avoid popsicles and flavored ices that may have been made with contaminated water.

- Eat foods that have been thoroughly cooked and are still hot and steaming.
- Avoid raw vegetables and fruits that cannot be peeled. Vegetables like lettuce are easily contaminated and are very hard to wash well.
- Peel raw fruits or vegetables themselves and do not eat the peelings.
- Avoid foods and beverages from street vendors.

For more information regarding international travel and hepatitis A, contact the CDC's Traveler's Health Office at 877.394.8747 or visit http://www.cdc.gov/travel.

Additional Information

Hepatitis A educational and technical resources including the NJDHSS *Hepatitis A Fact Sheet, Hepatitis A Vaccine Information Statement, Immunoglobulin Fact Sheet and Immunoglobulin Consent Form* are available on the NJDHSS Web site under Hepatitis A Technical Information.

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