



KAREN L. SMITH, MD, MPH
Director and State Health Officer

State of California—Health and Human Services Agency
California Department of Public Health



EDMUND G. BROWN JR.
Governor

**California Department of Public Health
HEALTHCARE PROVIDER ADVISORY – November 2, 2016**

**Recall of Frozen Strawberries from Egypt Potentially Contaminated
with Hepatitis A: Post-Exposure Prophylaxis Recommendations**

A large recall of frozen Egyptian strawberries that have been distributed widely in the United States, including California, has been issued due to the possibility of hepatitis A virus (HAV) contamination. The U.S. Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA), and state and local officials have been investigating an outbreak of HAV linked to frozen strawberries imported from Egypt.

For additional details about the investigation, please see the FDA website at:
<http://www.fda.gov/food/RecallsOutbreaksEmergencies/Outbreaks/ucm518775.htm>.
For information on product distribution in California, please see the CDPH website at:
<http://www.cdph.ca.gov/pubsforms/Documents/fdbFrICAPP1d.pdf>

Persons who do not need post-exposure prophylaxis (PEP) after exposure to recalled strawberries:

- Persons who are immune to HAV, i.e., those who have received at least one dose of single-antigen HAV vaccine, those who have had previous HAV infection, and those who are HAV IgG positive, do not need PEP.
- HAV vaccine has been routinely recommended for California children since 1999, and most children and young adolescents in California are immune to HAV.

Persons who should be considered for PEP after exposure to recalled strawberries:

- Persons who are susceptible to HAV who have eaten recalled strawberries in the past 14 days may be provided PEP.
- HAV PEP is a dose of single-antigen HAV vaccine or intramuscular (IM) immune globulin (IG) (0.02 mL/kg).

California Department of Public Health recommendations for HAV PEP for susceptible, exposed people:

| Age/years | <1* | 1-40 | 41-59 | 60-74* | 75+* |
|--|------|-------------------|-------------------|---|--------------------------------------|
| Healthy | IMIG | Vaccine preferred | Vaccine and/or IG | IMIG; vaccine if IMIG is in short supply or unavailable | IMIG; vaccine if IMIG is unavailable |
| Other† | IMIG | IMIG | IMIG | IMIG | IMIG |
| Consider vaccine plus IMIG for possible longer-term protection | | | | | |

*If IMIG is in short supply or unavailable, single-antigen HAV vaccine may be used for PEP in healthy people 60-74 years of age and in infants >6 months of age. If IMIG is unavailable, single-antigen HAV vaccine may be used for PEP in healthy people aged 75+ years.

†People who should receive IG for PEP regardless of age

CDC recommends that the following people, if susceptible, and regardless of age, receive IG PEP because they are at increased risk of severe HAV infection or may have a decreased immune response to vaccine. Vaccine may be given in addition to IG to potentially provide longer-term protection, but vaccine response may be limited. Clinical guidance should be obtained if patient’s immune status is unclear.

- Persons with chronic liver disease (e.g., cirrhosis)
- Immunocompromised persons, including persons:
 - With HIV/AIDS;
 - Undergoing hemodialysis;
 - Who have received solid organ, bone marrow or stem cell transplants;
 - Receiving high dose steroids (>2mg/kg/day);
 - Receiving chemotherapy, immune modulating and/or biologic medications‡, and

- Persons who are otherwise less capable of developing a normal response to immunization.

‡mercaptapurine, methotrexate, infliximab, adalimumab, etanercept, tacrolimus, mycophenolate, etc.

There is only one manufacturer of IMIG in the United States. GamaSTAN® is available in 2 mL and 10 mL single use vials. One source of IMIG is FFF Enterprises, which can be reached 24/7 at: 1-800-843-7477.

For more information, see:

https://www.cdph.ca.gov/programs/immunize/Documents/CDPH_HAV%20PEP%20Clinical%20Guidance.pdf
<https://www.cdph.ca.gov/programs/immunize/Documents/CdphHavIGPepGuidance.pdf>

Healthcare providers may use the screening tool below to evaluate patients for hepatitis A PEP:

(Adapted from Colorado Department of Public Health and Environment guidance)

| | |
|---|--|
| <p>Exposure: Did you eat strawberries at a restaurant or other facility on the list of facilities with recalled strawberries? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure <i>If yes, did you eat any of them in the last 14 days?</i> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure</p> <p><i>If person consumed recalled strawberries but not within the past 14 days, s/he will not be eligible for PEP. Counsel person on symptoms of HAV infection and ask them to contact you if they develop symptoms. Discontinue screening and do <u>not</u> administer PEP.</i></p> | |
| <p>Immunity: Have you ever been diagnosed with hepatitis A? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure Have you ever received the hepatitis A vaccine? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure <i>If yes: When? _____ How many doses? <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> Not sure</i> Have you received an immune globulin (IG or gamma globulin) shot in the last 3 months? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure <i>If yes: When? _____</i></p> <p><i>If person said “yes” to any of the above immunity questions, s/he will NOT need PEP. A previous history of HAV infection or HAV vaccination (at least one dose of single-antigen HAV vaccine, at least one month before exposure, is considered protection against HAV) . Discontinue screening and do <u>not</u> administer PEP.</i></p> | |
| <p>Recent illness: During the past two months have you had: Dark urine (like tea or a cola drink) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure Yellow skin or eyes <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure</p> <p><i>If person said “yes” to these symptoms questions, s/he should be evaluated for HAV infection before PEP is administered to determine if s/he possibly has HAV. See “Other healthcare provider recommendations” below.</i></p> | |

PEP eligibility: A person is eligible for PEP (vaccine or IMIG as appropriate) if all of the following criteria are met:

1. The person ate strawberries at a restaurant or other facility that served recalled strawberries.
2. The person ate the recalled strawberries within the last 14 days.
3. The person does not have a previous history of HAV infection or HAV vaccination. At least one dose of single-antigen HAV vaccine, at least one month before exposure, is considered protection against HAV.
4. The person has not had jaundice (yellow skin or eyes) or dark urine (like tea or cola) within the last two months.

Eligible for PEP: Yes No

Other healthcare provider recommendations:

1. Be alert for suspect cases of HAV, especially in patients with a history of consuming recalled strawberries. Clinical jaundice may be a late sign or one that never develops, particularly in children.
2. Order HAV IgM antibody serology rather than HAV total antibody serology when working up patients for acute disease. Total HAV antibody positivity may indicate immunity due to previous infection or immunization and is not sufficient evidence of an acute infection.
3. Avoid testing people who have no symptoms or elevated liver function tests, but report eating recalled strawberries. False positive HAV IgM test results are common when asymptomatic people are tested.
4. Advise patients in sensitive occupations not to work with suspected or confirmed HAV infection. Persons employed in food service, health care, or child care should not be allowed to work in these settings for at least one week after jaundice onset or two weeks after symptom onset (if no jaundice), whichever is later. These persons are at increased risk of spreading the infection to others via the fecal-oral route.
5. Promptly report all suspect and confirmed HAV cases to your local health department.