OREGON STATE PUBLIC HEALTH DIVIDION, DHS
IMMUNIZATION PROGRAM

IMMUNE GLOBULIN FOR THE PROPHYLAXIS OF HEPATITIS A

Revisions as of 7/06

- Addition of the ventrogluteal hip site as a choice for intramuscular injections of Immune globulin(IG). Instructions for how to administer a ventrogluteal intramuscular injection are attached to the Recommended Sites and Routes for Vaccine Administration Order.

I. ORDER:

1. Screen for contraindications.
2. Provide product information, answering questions.
3. Obtain a signed Vaccine Administration Record (VAR).
4. Give immune globulin (IG) intramuscularly (IM) to children and adults with a 1 to 2 inch needle, depending on recipient's weight.
5. Select a large muscle mass that can support the administration of a large volume of IG.
    - For children <3 years of age, administer IG into the vastus lateralis (outer thigh) muscle with a 7/8-to-1-inch needle.
    - For persons ≥3 years of age, administer IG into the ventrogluteal or dorsogluteal muscle with a 1-2 inch needle.
    - For adults with sufficient deltoid muscle mass, the deltoid muscle may be used.
6. Use formulation and dosage according to recipient's weight.
7. Do not administer more than 3 ml of IG per injection site in children and no more than 5 ml of IG per injection site in adults.
8. IG may be administered simultaneously with, or at any interval before or after any inactivated vaccine, including hepatitis A vaccine.

Note: Since 2 ml IG vials do not contain preservatives, discard opened vial after a single use regardless of whether entire amount of IG was given. Do not re-refrigerate.

Signature Health Officer or Medical Provider Date

II. RECOMMENDED POST-EXPOSURE PROPHYLAXIS

A. The confirmation of HAV infection in the index patient by IgM anti-HAV testing is recommended prior to providing postexposure prophylaxis to contacts. It is not recommended that contacts be serologically screened for immunity before giving IG and vaccine.

B. Contacts who have not previously been vaccinated should receive within two weeks of their last exposure:
   1. A single IM dose of IG (0.02 ml/kg).
   2. The first dose of hepatitis A vaccine (two-dose series.) Please refer to the standing order for Hepatitis A vaccine administration.
      Note: Vaccine and IG may be administered simultaneously at separate injection sites.

C. Persons who have received 1 dose of hepatitis A vaccine at least 1 month prior to exposure do not need IG.

D. Should cost constraints require a choice between IG and vaccine for post-exposure prophylaxis, IG should be offered.

E. **IG and vaccine should be administered to previously unvaccinated persons in the following situations**:
   1. Close personal contact: Administer to all household and sexual contacts of persons with serologically confirmed HAV infection.
   2. Day−care centers: Administer to all staff and attendees of day−care centers or homes if
      a) A case of Hepatitis A is confirmed in a child or employee, or
      b) Cases are recognized in two or more households of center attendees. In centers that do not provide care to children who wear diapers, IG and vaccine need to be given only to classroom contacts of an index case. When an outbreak occurs, (i.e., HAV cases in 2 or more households), IG and vaccine should also be considered for household members of diapered kids, depending on an epidemiological risk assessment. (See Hepatitis A Investigative Guideline)

II. RECOMMENDED POST-EXPOSURE PROPHYLAXIS, Continued

3. Food handlers and hepatitis A: In general, persons working as food handlers in Oregon are not at increased risk of hepatitis A infection when compared to the general public. Therefore, it is not currently recommended that food handlers without other risk factors be immunized. Some food handlers however, do have risks for hepatitis A and should be immunized for their own protection.
    - In the event that a food handler contracts hepatitis A, he/she may transmit the infection to others through food. A PHN and an environmental health specialist should assess the risk of transmission within the food-service facility. Should there be evidence of a risk of transmission of hepatitis A from an infected food handler to co-workers or others the local health authority should consider offering prophylaxis as appropriate.
    - In settings where repeated exposures to HAV may have occurred (e.g., institutional cafeterias), stronger consideration of IG and vaccine may be warranted. In the event of a common-source outbreak, IG should not be administered to exposed persons after cases have begun to occur because the 2-week period during which IG is effective will have been exceeded.

4. Common-source exposure: Because common-source transmission to patrons at a food establishment is unlikely, prophylaxis of patrons usually is not recommended; but it may be considered if the following are true:
    a. During the time when the food handler was likely to be infectious, the food handler both directly handled uncooked foods, or foods after cooking; and
    b. The food handler had diarrhea or poor hygienic practices; and
    c. Patrons can be identified and treated within 2 weeks of exposure.

5. Schools, hospitals, and work settings where epidemiologic investigation indicates transmission has occurred.

III. RECOMMENDED PRE-EXPOSURE PROPHYLAXIS FOR FOREIGN TRAVELERS

A. Primary immunization should be initiated at least 4 weeks prior to expected exposure to HAV.
- Persons can be assumed to be protected 4 weeks after receiving the first dose of vaccine, although the second dose 6−12 months later is needed for long-term protection.
- If immunization begins less than 4 weeks before expected exposure, IG (0.02 ml/kg) should also be given at a separate injection site.
- If vaccination is contraindicated, a single dose of IG (0.02 ml/kg) will confer short-term (1−2 months) protection.
- A larger single dose of IG (0.06 ml/kg) will confer 3−5 months of protection. This dosage may be repeated every 5 months.

B. IG is recommended for susceptible children <1 year of age who are traveling to high risk areas. Current HAV vaccines are not licensed for children less than one year of age.

C. IG produced by developing nations may not meet U.S. purity standards for plasma-derived products. Should persons need repeat doses of IG abroad, use IG produced by the U.S., or a product meeting the same standards.

IV. IG SCHEDULE FOR HEPATITIS A MANAGEMENT

Exposure	Dose	Duration of Coverage
Pre-exposure prophylaxis[1,2] AND Post-exposure prophylaxis[1,3]	0.02 ml/kg	1 1−2 months
Pre-exposure prophylaxis	0.06 ml/kg[4]	3−5 months

[1] IG should be administered as prophylaxis for Hepatitis A exposure in all susceptible (no history of disease, no history of immunization for HAV) children and adults who have been exposed within the past 14 days, or who plan travel to high-risk areas.

[2] If the person is traveling for longer than 6 months in areas where hepatitis A is common, a repeat dose is recommended 4 to 6 months after the first IG dose if the patient has not received hepatitis A vaccine.

[3] Must be administered within 2 weeks of exposure to a known HAV-IgM positive case. When IG is administered within two weeks of exposure, it is >85% effective in preventing hepatitis A infection.

[4] This dosage will offer longer protection for travelers who plan to reside in a Hepatitis A endemic area for longer than 2 months.

V. CONTRAINDICATIONS

A. IG should not be given to people with immunoglobulin A (IgA) deficiency. Persons with IgA deficiencies have the potential for developing antibodies to IgA and therefore could experience an anaphylactic reaction when IG is administered

B. IG should not be administered to persons with severe thrombocytopenia or any coagulating disorder that would contraindicate intramuscular injections.

C. IG should not be given to persons with a history of anaphylactic reaction (hives, swelling of the mouth or throat, difficulty breathing, hypotension or shock) to a previous dose of IG.

VI. PRECAUTIONS

A. Pregnancy: It is unknown whether IG can cause fetal harm when administered to a pregnant woman or if it could affect reproduction.

B. Careful administration in persons reporting a history of systemic allergic reaction following the administration of IG.

VII. SIDE EFFECTS AND ADVERSE REACTIONS

Event	**Frequency**
Soreness, tenderness, or pain at the injection site.	Occasionally

VIII. OTHER CONSIDERATIONS

A. PRE-VACCINATION SEROLOGIC TESTING:
   1. Children - Prevaccination testing of children is not indicated because of expected low prevalence of infection.
   2. Adults - The decision about whether to test should be based on cost of vaccination compared with the cost of the testing and whether testing is likely to interfere with initiating vaccination. In adults more than 40 years of age and in certain populations (e.g. American Indians, Alaskan Natives, and Hispanics) the prevalence may be high enough to warrant prevaccination testing.

B. Since 2 ml IG vials do not contain preservatives, discard opened vial after a single use regardless of whether entire amount of IG was given. Do not re-refrigerate.

C. IG may interfere with the response to live, attenuated vaccines (e.g. MMR, VARIVAX). Delay administration of live, attenuated vaccines for 5 months after the administration of IG.

D. Ideally, IG should not be administered for at least 2 weeks following the administration of MMR or for 3 weeks following varicella vaccine. Should this occur, the individual should be revaccinated, but no sooner than 5 months after IG administration.

E. When administering IG following exposure, and infection already has occurred, IG may modify the expression of the disease.

IX. REFERENCES

1. Hepatitis A. In: E*pidemiology and Prevention of Vaccine Preventable Disease,* ("Pink Book"). Atkinson W, Hamborsky J, Wolfe S, eds. 9th ed. Washington, DC: Public Health Foundation, 2006: 193-206.
2. Oregon State Public Health Division. Hepatitis A investigative guideline, updated April 2006.
   Available at: http://oregon.gov./DHS/ph/acd/reporting/guideln/hepa.pdf.
3. CDC. Prevention of Hepatitis A through active or passive Immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1999;48(RR-12):1-37.
4. Greenway K. Using the ventrogluteal site for intramuscular injection. Nurs Stand 2004;18: 39−42.
5. Nicholl LH & Hesby A. Intramuscular injection: an integrative research review and guideline for evidence-based practice. Appl Nurs Res 2002;15:149-62.
6. Immune Globulin package insert.

For more information or to clarify any part of the above order, consult with your health officer or contact the Oregon State Public Health Immunization Program at (971) 673-0300.

Visit our website at http://oregon.gov/dhs/ph/imm/index.shtml
To request this material in an alternate format (e.g., braille), please call (971) 673-0300.