



California Department of Public Health

SAMPLE PROTOCOL – JULY 2013



Intramuscular Immune Globulin (Human) USP for Hepatitis A Postexposure Prophylaxis

Intramuscular (IM) Immune Globulin (IG) is indicated for passive immunization to protect against hepatitis A virus infection after an exposure. An immunocompetent person who has received at least 1 dose of hepatitis A vaccine at least 4 weeks prior to exposure does not need to receive IG for postexposure prophylaxis. For additional recommendations on postexposure prophylaxis for hepatitis A, see: http://www.cdph.ca.gov/programs/immunize/Documents/CDPH_HAV%20PEP%20Clinical%20Guidance.pdf

ORDER:

1. Provide patient, parent or legal representative with the Hepatitis A Vaccine Information Sheet (VIS), which contains information about IG on the reverse side.
2. Screen for contraindications according to Table 2. The attached screening tool (Attachment 1) may be used (Courtesy of Massachusetts Department of Public Health).
3. **Always check the package insert prior to administration.**
Give IG 0.02 mL/kg intramuscularly (IM) with a 22-25-gauge needle.
 - a. For children and adults, administer IG in the upper outer quadrant of the gluteal muscle with a 1-2-inch needle, depending on the recipient’s weight. Direct the needle anteriorly to avoid injury to the sciatic nerve. The deltoid muscle may be used for adults when the dose of IG is not too large and there is sufficient muscle mass.
 - b. For infants, administer IG at a 90° angle in the anterolateral thigh with a 7/8- to 1-inch needle.

IG doses can be calculated based on an individual's weight (1kg = 2.2 lbs) or, in large clinic situations, the following table may be used as a guide:

Table 1. Suggested IG dose per Aggregate Weight Group

Weight	IG Dose
< 55 lbs (< 25 kg)	0.5 ml (or weigh each individual and calculate dose)
55 lbs – 110 lbs (25 kg – 50 kg)	1.0 ml
> 110 lbs to 220 lbs (> 50 kg – 100 kg)	2.0 ml
> 220 lbs (> 100 kg)	3.0 ml

Please note:

- IG should be administered at room temperature.
- At least 3 mL may be administered in one site in an adult or large child; 1 – 3 mL may be given in one site to small children and infants.

4. Administration of IG and other vaccines:
 - a. **Inactivated vaccines:** IG can be administered simultaneously with, or at any interval before or after, any inactivated vaccine, including hepatitis A vaccine.
 - b. **Live vaccines**
 - **If MMR and/or varicella vaccine has been given within the previous 2 weeks:**
The person should receive IG, but should be revaccinated or tested for seroconversion \geq 3 months later.

- **If IG for hepatitis A postexposure prophylaxis is given first:** The person should be told to wait 3 months before receiving MMR and/or varicella vaccine.

Note: IG can be administered at the same time as, or at any interval before or after, oral typhoid or yellow fever vaccines.

5. If possible, observe patient for an allergic reaction for 15 – 20 minutes after administering IG.
6. Facilities and personnel should be available for treating immediate hypersensitivity reactions.
7. Report clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or www.vaers.org.

Table 2. Contraindications and Precautions to IG

Valid Contraindications for Immune Globulin (IG)	Precautions
Anaphylactic reaction to a previous dose of IG	Previous anaphylactic reaction to latex ¹
History of IgA deficiency or reactions related to anti-IgA antibodies. (In such cases, use of IgA-depleted IGIV may reduce likelihood of further reaction.	Receipt of measles, mumps, rubella or varicella vaccine within the previous 2 weeks ²
	Mild to moderate bleeding disorder or taking anticoagulation medication ³
Persons with severe thrombocytopenia or any coagulation disorder that would preclude IM injection. In such cases, IGIV is preferred.	
IG may be given (not contraindicated) – if patient has: <ul style="list-style-type: none"> • Acute or chronic illness • Recent exposure to infectious disease • Current antimicrobial therapy • Pregnancy⁴ • Breast feeding • Contact allergy to latex 	

1. A person with a history of an **anaphylactic** reaction to latex should be referred to a healthcare provider for evaluation and safe administration of IG. For latex allergies other than anaphylactic allergies (e.g., history of contact allergy to latex gloves), vaccines supplied in vials or syringes that contain dry natural rubber or natural rubber latex can be administered.
2. IG now may interfere with the development of immunity to measles, mumps, rubella and varicella if given within 2 weeks after the vaccines. This person should still receive IG, but should be referred to their healthcare provider to be revaccinated with MMR or varicella vaccine or be tested for immunity at least 3 months after receipt of IG.
3. People with a mild to moderate bleeding disorder or taking anticoagulation medication should check with their healthcare provider before receiving IG in the clinic setting.
4. There is no known risk to the fetus from passive immunization of pregnant women with IG. IG should be given to pregnant women if it is indicated

**SAMPLE PROTOCOL - Immune Globulin (Human) USP For Hepatitis A
Postexposure Prophylaxis – Attachment 1**

Screening Tool for Administration of Immune Globulin
(IG) For Postexposure Prophylaxis for Hepatitis A

If IG is being administered as part of a hepatitis A outbreak, a question pertinent to exposure history may be inserted here. If the patient was exposed to hepatitis A within the last 2 weeks and IG is indicated because of age or underlying conditions, they should receive IG unless they are immunocompetent and have received at least 1 dose of hepatitis A vaccine at least one month before their exposure to hepatitis A virus.

Screening Questions	Response	Advice
1. Have you ever received hepatitis A vaccine?	No <input type="checkbox"/> Yes <input type="checkbox"/>	If you received at least 1 dose of hepatitis A vaccine at least one month before your exposure and have a healthy immune system, you are considered protected against hepatitis A and you do not need to receive IG.
2. Have you ever had a severe allergic (<u>anaphylactic</u>) reaction to a previous dose of IG?	No <input type="checkbox"/> Yes <input type="checkbox"/>	If yes, you should speak with your healthcare provider before getting IG.
3. Have you ever had a severe allergic (<u>anaphylactic</u>) reaction to latex?	No <input type="checkbox"/> Yes <input type="checkbox"/>	If yes, you should talk to your healthcare provider before getting IG. If you have only a <u>contact</u> or other non-serious allergy to latex, you can receive IG.
4. Have you ever had a reaction related to anti-IgA antibodies, or history of IgA deficiency?	No <input type="checkbox"/> Yes <input type="checkbox"/>	If yes, you should talk to your healthcare provider before receiving IG. They may choose to use IgA-depleted IG intravenously (IV) instead of IG given in your arm to reduce the likelihood of further reaction.
5. Do you have a bleeding disorder or take anticoagulant medication ('blood thinner')?	No <input type="checkbox"/> Yes <input type="checkbox"/>	If yes, you should talk to your healthcare provider before getting IG. They may decide it is okay for you to receive IG given in your arm, or they may decide you should receive it IV.
6. Have you received measles, mumps, rubella vaccine (MMR) and/or varicella (chicken pox) vaccine in the last 2 weeks?	No <input type="checkbox"/> Yes <input type="checkbox"/>	If yes, receiving IG now may interfere with immunity to measles, mumps, rubella and varicella. You should still receive IG today, but 3 months from now you should be revaccinated with MMR or varicella vaccine or be tested for immunity.
7. Do you plan to receive MMR and/or varicella vaccine in the next 3 months?	No <input type="checkbox"/> Yes <input type="checkbox"/>	You should wait 3 months after receiving IG before getting MMR or varicella vaccine.
8. Do you handle food that is served to people as part of your job or other activity?	No <input type="checkbox"/> Yes <input type="checkbox"/>	If yes, health department staff would like to speak with you. You may need documentation that you received IG in order to return to work.

Courtesy of Massachusetts Department of Public Health