



To: CAHAN San Diego Participants
Date: July 24, 2017
From: Public Health Services, Epidemiology and Immunizations Services Branch

Immune Globulin Dosage Increased for Hepatitis A Virus Prophylaxis

This health alert informs providers that Grifols Therapeutics, the manufacturer of GamaSTAN® S/D, the only formulation of human intramuscular (IM) immune globulin (IG) in the United States, has increased the recommended dosage for their product for the pre- and post-exposure prophylaxis of hepatitis A virus (HAV).

Situation

On July 7, 2017, Grifols Therapeutics increased the recommended dosages of its product (GamaSTAN® S/D) for pre- and post-exposure prophylaxis of HAV infection.

The newly recommended IG dose for HAV post-exposure prophylaxis (PEP) is 0.1 mL/kg, which is 5 times greater than the previously recommended dose.

The IG doses for pre-exposure prophylaxis for travel were also increased: 0.1 mL/kg for stays up to one month, 0.2 mL/kg for stays up to two months, and repeated boosters of 0.1 mL/kg every two months for stays beyond two months. Of note, prior to travel to countries with high or intermediate [endemic HAV transmission](#), active immunization with an available vaccine (Havrix®, Vaqta®, or Twinrix®) is preferred over IG under most circumstances.

The IG dosages were changed based on reportedly lower concentrations of anti-HAV antibodies in the product due to decreased prevalence of previous HAV infection among plasma donors. The provider letter from Grifols Therapeutics that outlines these changes is available [here](#).

California Department of Public Health (CDPH) guidance documents on the management of post-exposure prophylaxis (PEP) of HAV ([CDPH HAV PEP Quicksheet](#) and [CDPH HAV PEP Administration](#)) have been updated to reflect these changes.

San Diego County is currently experiencing a large HAV outbreak. As of July 20, 2017, 260 cases have been reported, including six deaths. Detailed recommendations for the outbreak may be found at the [County Hepatitis A website](#), which has weekly updates on the case count and copies of all health alerts regarding HAV. Santa Cruz County is also experiencing an HAV outbreak with at least 27 cases. In both counties, most of the infected persons have been homeless and/or users of illicit drugs.

Recommendation

Providers should immediately use the increased IG dosage (0.1 mL/kg) when indicated for HAV post-exposure prophylaxis (PEP).

Susceptible people exposed to HAV should receive a dose of single-antigen HAV vaccine (Havrix® or Vaqta®) and/or intramuscular (IM) IG (0.1 mL/kg) as soon as possible within two weeks of last exposure. The combination HAV/hepatitis B vaccine (Twinrix®) should not be used for PEP.

This table, adapted from CDPH guidance, may be utilized to determine which products to use to prevent HAV in exposed persons.

Age/years	<1†	1-40	41-59	60-74†	75+
Healthy	IG Only	Vaccine preferred	Vaccine	IG + vaccine	IG + vaccine
Other‡	IG	IG	IG	IG	IG

†When IG is unavailable or in short supply, single-antigen HAV vaccine may be used for PEP in healthy people 60- 74 years of age and in infants >6 months of age.

‡Other medical conditions are defined at:

https://archive.cdph.ca.gov/programs/immunize/Documents/CDPH_HAV%20PEP%20Clinical%20Guidance.pdf

Persons administered IG for whom HAV vaccine is also recommended for other reasons (including ongoing exposure during the current outbreak) should receive a dose of HAV vaccine simultaneously with IG.

Persons who were exposed less than two weeks ago and who have recently received a dose of IM IG less than 0.1 mL/kg may receive an additional dose for a total of 0.1 mL/kg.

Questions about HAV reporting and prophylaxis (including IG dosage) may be directed to the County Epidemiology Program at 619-692-8499 (Monday-Friday, 8 AM-5 PM), or 858-565-5255 (after hours, during weekends, and on County-observed holidays).

Thank you for your continued participation.

CAHAN San Diego

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