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This policy is amended by HA Policy [97-047](#)



THE ASSISTANT SECRETARY OF DEFENSE  
WASHINGTON, DC 20301-1200

AUG 12 1996

**MEMORANDUM FOR:** SECRETARY OF THE ARMY (M&RA)  
SECRETARY OF THE NAVY (M&RA)  
SECRETARY OF THE AIR FORCE (MRAI&E)

**SUBJECT:** Policy for Use of Hepatitis A Virus (HAV) Vaccine and Immune Globulin (IG)

In April, 1995, I directed the Services to begin using HAV vaccine in accordance with recommendations from the Armed Forces Epidemiological Board (AFEB). Recently, the principal manufacturer of immune globulin (IG) has recalled its product from the market. This development, as described in the attached fact sheet, has created a national shortage with major implications for the military use of IG for deployment and clinical purposes. Therefore, I am directing you to accelerate HAV vaccine immunization efforts, and to restrict IG use only in clinical situations where it is absolutely needed.

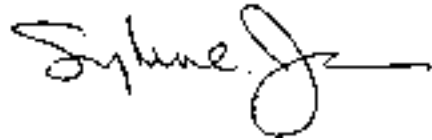
Effective immediately, it is DoD policy that HAV vaccine is the regimen of choice for pre-exposure prophylaxis against HAV infection. HAV vaccine rather than IG will be used for pre-exposure prophylaxis unless a specific situation exists which requires immediate passive immunity. Other indications for IG include postexposure prophylaxis and a variety of other specific clinical situations.

The department has established a goal of achieving HAV immunization of the total Active Duty and Selected Reserve force by December 31, 1998. Military personnel and, in some instances, family members should be immunized in the following order or priority:

- Military personnel currently assigned or deployed to high risk areas
- Military personnel including National Guard/Reserve members on mobility status who are targeted for early deployment to high risk areas
- Family members and DoD employees assigned to, or traveling to high risk areas
- Accessions and new recruits into the Armed Forces
- Other Active Duty and Selected Reserve personnel

Compliance with this policy will ensure consistency within the Department regarding the use of HAV vaccine and IG, and facilitate logistical and fiscal planning. The Services shall provide their implementation plans to this

office within 90 days. My point of contact in this matter is Colonel Chip Patterson, USAF, MC, who may be reached at (703) 695-7116.



Stephen C. Joseph, M.D., M.P.H.

Attachment:

As Stated

cc: Surgeons-General

**HA POLICY 96-054**

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### **Manufacturer Withdrawal of Immune Globulin (IG)**

The Department of Defense is a major consumer of immune globulin (IG) which is routinely administered to military personnel to prevent Hepatitis A virus (HAV) disease. In June, 1996, the Food and Drug Administration (FDA) requested that manufacturers test lots of IG for the presence of Hepatitis C virus (HCV) RNA, using advanced polymerase chain reaction (PCR2) methods. Centeon, the primary supplier of IG used by DoD, initiated a voluntary recall of its product rather than conduct the tests. The product remains licensed by the FDA. In response to the recall by Centeon, the Defense Personnel Support Center (DPSC) through the Defense Medical Standardization Board (DMSB) notified the Services to suspend all IG stocks.

Immune globulin preparations approved in the U.S. for intramuscular (IM) use have not been implicated in the transmission of HCV. However in February 1994, one intravenous (IV) immune globulin product was implicated in the transmission of HCV during the prior year and was removed from the market. Although the reasons for transmission by this product have not been determined, a combination of factors may have been responsible, including lack of a viral inactivation/removal step as part of the manufacturing process, changes in donor screening since 1992, and the manufacturing method.

FDA has been working with manufacturers to implement the addition of a viral inactivation step for all immune globulin products. Since December 1994, FDA has recommended that lots of IG be tested for HCV by PCR and that lots found positive be withdrawn from circulation. To date, transmission of HCV via intramuscular administration of IG has not been documented and available epidemiologic evidence does not support transmission. In a review of this issue last year, prior to the recall, Centers for Disease Control and Prevention (CDC) advised that administration of immune globulin products should not be withheld when medically indicated; and recommended against retrospective serologic surveys of past IG recipients. The PCR2 testing technique now required by FDA provides enhanced sensitivity to detect HCV RNA sequences compared to the original PCR test.

The Department's primary response to the recall is an accelerated effort to immunize military personnel with

HAV vaccine thereby decreasing requirements to use IG for preexposure prophylaxis. However, limited amounts of IG will still be needed for preexposure prophylaxis (special situations may preclude use of HAV vaccine), postexposure prophylaxis, and other clinical indications. Therefore, DPSC is retaining two lots of IG currently in the depot system which the FDA has tested negative for HCV using PCR2 technology. These existing IG stocks will be distributed through the medical logistics field offices in consultation with their Service's designated preventive medicine advisor. Limited amounts of IG which meet the current FDA viral inactivation standards may be available from other sources, and clinicians should attempt to obtain these products if at all possible. Information regarding these other sources will become available through the DMSB.

Information from the Centers for Disease Control and Prevention (CDC) regarding use of HAV vaccine for international travelers and clinical indications for IG prophylaxis has previously been issued in Morbidity and Mortality Weekly Report (MMWR).1995:44:559-560 and MMWR.1990:40(S-2):1-5. Regarding the current situation, CDC plans to issue specific guidance concerning prioritization and clinical indications for the use of IG.

## **RECOMMENDED GUIDELINES FOR THE USE OF IMMUNE GLOBULIN**

1. The market withdrawal of Immune Globulin (IG) intramuscular injection by Armour Pharmaceutical division of Centeon has created a critical national shortage of this product which is used to prevent infection by Hepatitis A virus (HAV). In order to clarify the situation, the following guidance is provided:

- a. Activities holding IG withdrawn from the market by Centeon (Armour) should return them (all lots and all vials) to the manufacturer. Contact Centeon at (800) 201-3960 or 610-878-4100; and, FAX 610-878-4007.
- b. As directed by the Office of the Assistant Secretary of Defense (Health Affairs), the Defense Personnel Supply Center (DPSC) will maintain two lots of IG which will be held in reserve for urgent clinical situations which include:

### **HAV Pre-exposure prophylaxis**

(1) Units planning deployments to areas with a high risk of HAV exposure should rely upon using HAV vaccine rather than IG to achieve pre-exposure immunity against HAV infection. After receiving the initial dose of HAV Vaccine, persons are considered to be protected by 4 weeks. However, concurrent administration of IG (at a different injection site) may be indicated if significant fecal-oral exposure through person-to-person contact or ingestion of contaminated food or water is probable within 4 weeks of the initial vaccine dose. Requests for routine use of IG as pre-exposure prophylaxis for deployment situations will be denied unless there are extenuating mission-related circumstances which warrant its use.

(2) Strict adherence to command directed, field implementation of doctrinal preventive measures in food and water sanitation and waste disposal can significantly reduce the risk of HAV infection during operations in countries where there is a high prevalence of the disease. General information regarding the use of HAV vaccine for international travelers is contained in

Morbidity and Mortality Weekly Report (MMWR).1995;44:pp 559-560.

### **HAV Post-exposure prophylaxis**

(1) Close personal contact: IG is recommended for all household and sexual contacts of persons with hepatitis A.

(2) Day-care centers: IG should be recommended to all staff and attendees of day-care centers or homes if: (a) one or more children or employees are diagnosed as having hepatitis A, or (b) cases are recognized in 2 or more households or center attendees. When an outbreak involving 3 or more families occurs, IG should be considered for households that have children (center attendees) in diapers. In centers not enrolling children in diapers, IG need only be given to classroom contacts of an index case.

(3) Common-source exposure: IG might be effective in preventing foodborne or waterborne HAV disease if it is administered within 2 weeks of the known exposure.

Medical staff should refer to MMWR.1990;39(S-2): pp 1-5 for a complete description of these and other clinical indications regarding use of IG for post-exposure prophylaxis.

### **Other Clinical Indications for IG Use**

(1) IG is indicated for prophylaxis and/or treatment for other clinical conditions besides HAV infection. These other indications are described in ImmunoFacts: Vaccines & Immunologic Drugs (May, 1996); pp 207-21, and Recommendations of the Immunization Practices Advisory Committee (ACIP) MMWR.1993;42(RR-5): pp 9-10.

#### **c. Activities which urgently require orders for IG must:**

(1) Place their request through their respective Service Medical Logistic Field Office (USAMMA, AFMLO, NMLC). Patient names and a brief narrative summarizing the reasons for the request must be available for submission with the order.

(2) The Service Medical Logistic Field Office duty officer will consult with their Service Preventive Medicine point of contact, and only honor requests which meet the urgent use criteria described in 1.b above.

Army Preventive Medicine:  
LTC R. Defraites, MC, USA  
(703) 681-3160 or DSN 761-3160

Navy Preventive Medicine:  
CDR K. Hayashi, MC, USN

(804) 363-5606 or DSN 864-5606

Air Force Preventive Medicine:  
Lt Col M. Parkinson, USAF, MC  
(202) 404-1835 or DSN 297-1835

Marine Corps Preventive Medicine:  
CDR T. Sharp, MC, USN  
(703) 614-4478 or DSN 224-4478

(3) The order will be called into the Emergency Supply Operation Center (ESOC) at DPSC as a PRIORITY #3 by the Service Medical Logistic Field Office.

(4) ESOC will not accept orders for IG without the Service Medical Logistic Field Office clearance.

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Last update: 1/11/1999