



DEPARTMENT OF THE ARMY
HEADQUARTERS, U.S. ARMY MEDICAL COMMAND
2050 WORTH ROAD
FORT SAM HOUSTON, TEXAS 78234-6000



REPLY TO
ATTENTION OF

MCHO-CL-W (40a)

22 MAY 1995

MEMORANDUM FOR

Commanders, MEDCOM HSSAs (Prov)
Commander, DENCOM
Commander, VETCOM

SUBJECT: Use of Havrix® (Hepatitis A Vaccine, Inactivated)

1. References:

a. Memorandum, Armed Forces Epidemiological Board, 28 February 1995, subject: Recommendations Regarding the Use of the Newly Licensed Hepatitis A Vaccine in Military Personnel.

b. Package Insert, Havrix® (Hepatitis A Vaccine, Inactivated), SmithKline Beecham Pharmaceuticals.

2. Ensure dissemination to all Preventive Medicine, Internal Medicine, Family Practice, Pediatrics, Immunization, Ambulatory Care, Pharmacy, and Medical Logistics organizations in your area of responsibility.

3. Havrix® (Hepatitis A Vaccine, Inactivated) was recently licensed by the Food and Drug Administration for use in humans. This memorandum outlines Army policy for its use to prevent the occurrence of Hepatitis A virus infection among eligible beneficiaries. Another formulation is expected to be licensed within the next 12 months. This policy will be reevaluated and revised at that time.

4. Havrix® is available in the following formulations:

- a. Adult prefilled syringe, NSN 6505-01-397-6045, Cost \$32.59 per dose.
- b. Adult single dose vial, NSN 6505-01-398-3502, Cost pending.
- c. Pediatric formulation, single dose vial, NDC 58160-836-01, cost \$11.17 per dose.

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5. Dosage and Administration:

a. Adults. 2 dose series. Primary immunization consists of a single 1 mL dose by intramuscular (IM) injection in the deltoid region. The vaccine should not be administered in the gluteal region. A second dose is recommended between 6 and 12 months later to ensure the highest antibody titers. This series provides protection for at least 4 years. The need for periodic boosters is still being investigated.

b. Children (ages 2-18). 3 dose series. Primary immunization consists of two doses, 0.5 mL each, given 1 month apart, IM in the deltoid or thigh muscles with a booster dose recommended between 6 and 12 months later.

c. Side effects are minimal. Soreness at the injection site is fairly common and headache occurs occasionally.

6. Havrix® has been shown to be safe and highly effective in preventing Hepatitis A virus infection. Within 2-3 weeks of the first dose, Havrix® produces active immunity which is much longer lasting (at least 4 years) than the passive immunity afforded by injections of immune globulin (IG) (3-5 months).

7. Compared to IG, Havrix® offers other advantages.

a. Injection can be given well in advance of the anticipated exposure to Hepatitis A, but IG is usually given just before exposure. This feature would permit more methodical preparation of military personnel for deployments and minimize the impact of just-in-time administration of IG.

b. Shortages of IG can be expected and acquisition costs of IG are likely to rise. Problems such as the recent IG recall to test for Hepatitis C RNA also make IG less desirable and available.

8. Although widespread use of Havrix® in the general United States population would be an ideal goal, the high cost of the vaccine makes such use at this time not economically feasible. In view of this, its use in the Army should be reserved for situations in which immunity to Hepatitis A infection is deemed critical because of anticipated high risk of exposure. The priorities described below represent a framework within which decisions to use Havrix® should be made. Pre-vaccination screening for susceptibility to Hepatitis A infection is not necessary although

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it may be desirable if a group is to be immunized and it is felt that the prevalence of Hepatitis A antibody seropositivity (i.e., immunity) is likely to be relatively high (>15 percent).

9. Risks of acquiring Hepatitis A infection are highest for travelers to, or residents of, areas where prevailing sanitary conditions are less than optimal. Such factors increase the likelihood that susceptible persons will become infected via contaminated food or water. Although Hepatitis A infection is not rare anywhere in the world, highly industrialized countries (Western Europe, North America, Japan, Korea, and Australia) are generally not considered to be high risk areas because of the prevailing higher levels of sanitation. Developing countries, on the other hand, if they have high rates of Hepatitis A infection among the residents, should be regarded as areas for which travelers should be given the benefit of immunological protection against Hepatitis A. Havrix® or IG provide this protection; and in general, Havrix® should be considered if protection is required for greater than 5 months.

10. Havrix® should be administered according to the following priority:

a. Soldiers who are being assigned or deployed for periods longer than 5 months to, or who will repeatedly travel to, geographic areas with known high risk of Hepatitis A infection. For nonrecurring travel to such areas for periods less than 5 months, IG should be used.

b. Soldiers, active and reserve, assigned to units with contingency missions for rapid deployment to high risk areas.

c. Family members and government employees who will reside for longer than 5 months in, or have repeated travel to, high risk areas. As stated in paragraph 10a, above, IG should be used for onetime travel of less than 5 months to high risk areas.

d. Persons with occupational risk of Hepatitis A infection, such as care givers in institutions for the developmentally challenged and those who work with experimentally Hepatitis A-infected nonhuman primates or with Hepatitis A virus in a laboratory setting. Other occupational groups in the U.S., such as health care workers, sewage treatment plant workers, food handlers, and day-care workers, have not been shown to be at increased risk of Hepatitis A infection and should be regarded as falling into the category described in paragraph 10g, below.

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- e. New accessions to the Army.
- f. All other soldiers.
- g. All other beneficiaries 2 years of age and older.

11. At this time, economic constraints make it unlikely that groups listed in paragraphs 10e through 10g, above, can be routinely immunized. Funds for Havrix® have been requested. For the present, costs will have to be borne out of core operating budgets. If this should change, medical units will be advised. In the meantime, immunization should be confined to groups listed in paragraphs 10a through 10d, above.

12. The IG will continue to have utility in the prevention of Hepatitis A infection. The IG is a much more cost-effective way to provide protection against Hepatitis A to individuals for whom potential exposure is expected to be of short duration and nonrecurring. Furthermore, IG offers immediate immunologic protection against Hepatitis A in situations where exposure may have already occurred (post-exposure prophylaxis). Examples of applicable situations:

a. Pre-exposure prophylaxis: Onetime travel for less than 5 months to a high-risk geographic area.

b. Post-exposure prophylaxis:

(1) Close, personal contact (household, sexual) with a person with confirmed Hepatitis A infection. (If such exposure is expected to continue for several months, give Havrix® as well.)

(2) Occurrence of a case of Hepatitis A in a worker or child in a day-care center.

(3) Food-borne or water-borne exposure to Hepatitis A.

(4) Outbreaks in limited, well-defined settings such as workplaces, schools, or day-care centers.

13. Our point of contact is LTC Oliverson, Occupational Medicine Staff Officer, DSN 471-6337 or Commercial (210) 221-6337, and at the U.S. Army Center for Health Promotion and Preventive

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