INFORMATION PAPER

Military Vaccine Agency
1 March 2007

SUBJECT: Hepatitis B Infection and Hepatitis B Vaccine

1. Purpose. To describe hepatitis B virus, hepatitis B infection, and the vaccine to prevent it.

2. Facts.

a. Microbiology. Hepatitis B is a serious liver disease caused by the hepatitis B virus (HBV). In the short term, hepatitis B is an acute illness that can cause loss of appetite, diarrhea, vomiting, redness, jaundice (yellow skin or eyes) and pain in the muscles, joints, and stomach. Long term, it can cause a life-long infection, cirrhosis or scarring of the liver, liver cancer, liver failure, and even death.

b. Epidemiology. The hepatitis B virus is transmitted through direct contact with the blood or body fluids of someone infected with hepatitis B. The virus is also transmitted by having unprotected sex, sharing needles while injecting illegal drugs, by being stuck with a used needle, and from an infected mother to her baby during birth. About 1/3 of people who are infected with the hepatitis B virus in the United States are unaware of it. The vaccine is recommended for all ages and especially for people at higher risk. At-risk groups include: people traveling to high-risk areas (e.g., Korean peninsula, regions of Africa, Asia); healthcare personnel; laboratory workers handling blood and patient specimens; police, fire and emergency medical personnel who give first-aid treatment; people with blood-clotting disorders (e.g., hemophilia); people who have household contacts infected with the virus; people with multiple sex partners; men who have sex with men; and people who have a sexually transmitted disease.

c. Vaccine. Ideally, vaccination should begin at least 6 months before travel so the full vaccine series can be completed before departure. Because some protection is provided by one or two doses, the vaccine series should be initiated, if indicated, even if it cannot be completed before departure. Hepatitis B vaccine is 80% to 95% effective in preventing HBV infection and clinical hepatitis among susceptible children and adults. If a protective antibody response develops after vaccination, vaccine recipients are virtually 100% protected against clinical illness. The vaccine is safe and effective for infants, children, and adults.

(1) Two hepatitis B vaccines are marketed in the United States: *Engerix-B*® (GlaxoSmithKline) and *Recombivax-HB*® (Merck). Both vaccines are supplied as sterile suspensions for intramuscular injection. Several combination vaccines that protect against hepatitis B infection are also licensed. *Engerix-B*® is combined with hepatitis A vaccine in a formulation called *Twinrix*® (GSK). *Recombivax-HB*® is combined with *Haemophilus influenzae* type b (Hib) vaccine in a formulation called *Comvax*® (Merck). *Pediarix* ® (GSK) contains DTaP, hepatitis B, and inactivated poliovirus vaccines.

(2) Please see additional information paper on counting combined regimens of Twinrix® and separate hepatitis A and hepatitis B vaccines at:
http://www.vaccines.mil/documents/1031MIP-Twinrix.pdf.

d. Immunization. See each vaccine's recommended dosages and administration schedules, which are based on maternal hepatitis-B infection status, age, and health condition (e.g., hemodialysis). People typically receive three intramuscular doses over a 6- to 12-month period. The second dose should be given 1 month after the first dose; the third dose should be given at least 2 months after the second dose and at least 4 months after the first dose. The dose is age- and brand-dependent. The adult dose of *Engerix-B*® is 20 mcg per 1 ml, typically on a 0, 1, 6 month schedule. The adult dose of *Recombivax-HB*® is 10 mcg per 1 ml, typically on a 0, 1, 6 month schedule.

e. Cautions. The following people should not receive hepatitis B vaccine: those with known severe hypersensitivity to the vaccine or to one of its components (e.g., yeast); those have a moderate to severe acute illness. Hepatitis B infection has a long incubation period, so it is possible for a person to have unrecognized hepatitis B infection before vaccination and therefore should wait until acute illness is resolved before receiving vaccination.

f. Adverse Events. The most common adverse reactions after hepatitis B vaccination are irritation, redness, swelling, warmth, itching, and bruising at the injection site; and systemic effects (e.g., headache, fever, myalgia, malaise). More serious reactions, which are rare, include tingling of the hands or feet, difficulty moving, stiffness, skin rash, difficulty breathing, chest pain, or vision problems.

g. DoD Policy. Unless already immune, administer hepatitis B vaccine to susceptible military personnel with the second cluster of immunizations during initial entry training, as well as military personnel susceptible based on occupation or behavior, or deploying for more than 30 days to areas of high hepatitis B endemicity (for example,
portions of Asia).

3. References.

a. Advisory Committee on Immunization Practices. Hepatitis B virus: A comprehensive Strategy for eliminating transmission in the United States. *MMWR* 2005; 54(RR-16):1- 23. www.cdc.gov/ncidod/diseases/hepatitis/v40rr13.htm

b. CDC disease information. www.cdc.gov/ncidod/diseases/hepatitis/b/index.htm

c. Multiple resources (e.g., product insert, Vaccine Information Statements) assembled by the Military Vaccine Agency: www.vaccines.mil/HepB

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