INFORMATION PAPER

Military Vaccine Agency
16 April 2012

SUBJECT: Hepatitis A Infection and Hepatitis A Vaccines

1. Purpose. To describe hepatitis A virus, and the vaccines to prevent it.

2. Facts.

a. Microbiology. Hepatitis A virus (HAV) is a single-stranded RNA picornavirus. Picornaviruses are non-enveloped, positive–stranded RNA viruses with an icosaheral capsid. A capsid is the protein shell that encloses the genetic material of the virus. Once the virus has infected the cell, it will start replicating using the mechanisms of the infected host cell. The primary site of HAV replication is in the liver where it is shed into the billiary ducts and eventually excreted in the feces.

b. Disease. The incubation period for HAV is approximately 28 days. The acute onset of symptoms may include fever, fatigue, loss of appetite, nausea, jaundice (yellow skin or eyes), abdominal pain, and dark urine. Acute illness typically does not last more than 2 months but some individuals may relapse.

c. Epidemiology. Humans are the only natural reservoir of the virus. HAV is usually spread through direct person-to-person contact or after a person ingests the virus from contact with objects, food, or drinks contaminated by feces or stool from an infected individual. HAV occurs throughout the world and is most common in areas with poor food, water, and sewage sanitation. It is endemic in some areas, particularly Central and South America, Africa, the Middle East, Asia, and the Western Pacific. HAV is one of the most common infections acquired during travel. Risk is highest for those who live in or visit rural areas, trek in the backcountry, or frequently eat or drink in settings of poor sanitation.

d. Vaccine.

1) Merck & Company's vaccine, VAQTA®, is an inactivated whole-virus vaccine. The cell culture adapted virus is propagated in human fibroblasts and then inactivated with formalin, and adsorbed to an aluminum hydroxyphosphate sulfate. All formulations of the vaccine are preservative free.

2) GlaxoSmithKline's vaccine, HAVRIX®, is an inactivated whole-virus vaccine. The cell culture adapted virus is propagated in human diploids and then inactivated with formalin, and adsorbed to an aluminum hydroxide adjuvant. All formulations of the vaccine are preservative free.

3) GlaxoSmithKline's vaccine, TWINRIX®, is a bivalent vaccine of inactivated hepatitis A virus and purified surface antigen of the hepatitis B virus. Each dose of contains residual formalin, human diploid proteins, neomycin sulfate and yeast protein. All formulations of the vaccine are preservative free.

e. Cautions. The hepatitis A vaccine should not be administered to individuals with a history of serious allergic reaction to a previous dose or to any component of the vaccine to include neomycin or yeast (TWINRIX® only). Use caution when vaccinating latex-sensitive individuals since all three vaccine prefilled syringe plungers and the tip caps contain dry natural latex rubber that may cause allergic reactions. All of the vaccine vials stoppers are latex free. It is recommended that those who are moderately or severely ill, or have an infection should postpone vaccination until they recover unless at risk for HAV infection. Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished immune response. Syncope can occur in association with vaccination and procedures should be in place to avoid falling injury.

f. Immunization.

1) Administer HAVRIX® or VAQTA® as a two dose series with at least six months between the first and second dose. The pediatric (12 months - 18 years) dose is 0.5-mL and the adult (≥19 years) dose is 1-mL, both are administered as an intramuscular injection. The vaccines are interchangeable and licensed for persons ≥12 months of age. The primary immunization should be administered at least two weeks prior to expected exposure to HAV.

2) TWINRIX® is a three dose series administered at 0, 1, and 6 months. Alternative series timing should be in accordance with the package insert or ACIP guidelines. Each dose is 1-mL administered as an intramuscular injection in the deltoid.

3) See the additional information paper on completing vaccine series with either Hep A/Hep B combination vaccine or the monovalent hepatitis A and hepatitis B vaccines at: www.vaccines.mil/document/1504MIP-Hep%20A-B%20Counting%20Doses.pdf.

g. Adverse Events. The most commonly reported adverse reaction following vaccination is injection site pain, erythema, and swelling. The symptoms are generally mild and self-limited. Mild systemic complaints to include headaches, malaise, fatigue, and low-grade fever are reported by fewer than 10% of recipients.

h. DoD Policy. Unless seroimmune, administer hepatitis A vaccine to military personnel at initial entry training or upon deployment to hepatitis A endemic areas.

3. References.

a. Centers for Disease Control and Prevention. Prevention of Hepatitis A through Active or Passive Immunization. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2006;55(RR07):1-23. www.cdc.gov/mmwr/preview/mmwrhtml/rr5507a1.htm.

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

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