

INFORMATION PAPER

DHA-IHB
3 Nov 2015

SUBJECT: Japanese Encephalitis and Japanese Encephalitis Vaccine

1. Purpose. To describe Japanese Encephalitis Virus and the vaccine to prevent it.

2. Facts.

a. Microbiology. Japanese Encephalitis Virus (JEV) is a single-stranded RNA virus that belongs to the genus *Flavivirus*, and is closely related to West Nile and St. Louis encephalitis viruses. Four genotypes of JEV have been identified.

b. Disease. Incubation is on average 5-15 days and begins with acute onset of fever, headache, and vomiting. Less than 1% of individuals infected with JEV develop clinical disease. JEV may result in an acute infection of the brain, spinal cord, and lining of the brain (meninges) with high rates of complications, chronic disability, and death. Additional neurologic symptoms may begin to develop as well. Japanese encephalitis (JE) has a case-fatality ratio of approximately 20-30% with 30-50% of JE survivors having neurologic or psychiatric sequelae even years later.

c. Epidemiology. JEV is an arthropod-borne virus transmitted by the bite of various species of *Culex* mosquitoes. The disease is most common in rural, agricultural areas of Asia, as well as, certain western Pacific Islands, where mosquito larvae are found in flooded rice fields and marshes. Transmission is highest in the summer and fall. Domestic pigs are the most important source of infection for mosquitoes that transmit JEV to humans

d. Vaccine. IXIARO® Japanese Encephalitis Virus vaccine (adsorbed) is manufactured by Intercell Biomedical. Currently, it's the only FDA-approved vaccine for JEV prevention in the United States. IXIARO® is a sterile purified vero cell-cultured inactivated vaccine. The formulation does not include preservatives, stabilizers or antibiotics. IXIARO® is a clear liquid with white precipitate; when shaken before use, a white/cloudy suspension forms.

e. Cautions. People should not receive the JEV vaccination if they have known hypersensitivity to the vaccine, or its components. IXIARO® contains protamine sulfate, a compound known to cause hypersensitivity reactions in some individuals. Individuals who show hypersensitivity reactions after receiving the first dose of the vaccine should not be given the second dose. Defer vaccination in people with moderate to severe acute illness. Safety and effectiveness of JEV vaccine have not been established in pregnant women. Use in pregnancy should be considered with clinical consultation of potential risk and benefit.

f. Immunization. IXIARO® is licensed for individuals ages 2 months and older. It is administered as a two-dose series, with the second dose at least 28 days after the first dose. Administer a 0.25ml dose to children ages 2 months through 3 years, intramuscularly in the anterolateral thigh. Carefully follow the steps outlined in the package insert to prepare the 0.25ml pediatric dose. Administer a 0.5 ml dose to children ages 3 years and older and adults, intramuscularly in the deltoid region.

(1) A single booster dose is recommended for individuals ages 17 years and older. The booster dose is administered at least one year after completion of the two-dose series. The safety and immunogenicity of a booster dose in children 2 months through 16 years have not been evaluated, therefore a booster dose is not recommended at this time. It is recommended that persons who previously received JE-VAX® (an older JEV vaccine formulation that is no longer available in the United States) and require further vaccination should receive a two-dose primary series of IXIARO®.

(2) Vaccination should be completed at least one week prior to potential exposure to JEV, whenever possible.

g. Adverse events. Local injection site reactions may include pain and swelling. The most common systemic effects observed in adults after immunization with IXIARO® are headache and myalgia. The most common systemic effects observed in children after immunization with IXIARO® are fever, irritability, and diarrhea. Vaccine recipients should be observed for 30 minutes after immunization and warned about the possibility of delayed allergic reactions. All serious adverse events should be reported to the Vaccine Adverse Events Reporting System (VAERS).

h. DoD policy. Administer JEV vaccine to personnel deploying to PACOM in accordance with PACOM Force Health Protection Guidance. In addition, vaccination is highly recommended for service members, DoD civilians and beneficiaries who will be stationed or visiting for more than 30 days in endemic areas, to include those based in urban settings with travel to rural areas. Vaccination is recommended for short-term (<1 month) travelers to endemic areas if they plan to travel outside of the urban areas; travelers to areas with ongoing outbreaks; and travelers to endemic areas who are unsure of travel itineraries/destinations.

3. References.

a. Centers for Disease Control and Prevention. Japanese Encephalitis Vaccines – Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2010; 59(No. RR-1):1-32

b. Centers for Disease Control and Prevention. Recommendations for Use of a Booster Dose of Inactivated Vero Cell Culture-Derived Japanese Encephalitis Vaccine – Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2011; 60(20): 661-663 Military Vaccine Agency

c. Centers for Disease Control and Prevention. CDC Health Information for International Travel 2012. Atlanta: U.S. Department of Health and Human Services, Public Health Service, 2011

d. Multiple resources (e.g., product insert, Vaccine Information Statements) assembled by the Defense Health Agency immunization Healthcare Branch
www.health.mil/JEV

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