Japanese encephalitis Vaccination Program
Questions and Answers

Prepared by

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Disease
- Overview
- Symptoms
- Complications

Vaccine
- Overview
- Administration
- Contraindications
- Special Considerations

Adapted from the Immunization Action Coalition (with permission) and the Centers for Disease Control and Prevention (CDC).

Disease

Overview

1) What is Japanese encephalitis (JE)?
A severe infection of the brain and spinal cord caused by the bite of a Culex mosquito carrying the JE virus. The disease is most common in rural, agricultural areas of east and southeast Asia (e.g., Okinawa, Burma, Cambodia, Laos, Thailand) where mosquito larvae inhabit flooded rice fields and marshes. These mosquitoes feed outdoors from dusk until dawn. Transmission is highest in summer and fall.

Japanese encephalitis is not transmitted from person-to-person. It is the leading cause of viral encephalitis in Asia with 30,000 to 50,000 cases reported annually.

2) Who is at risk for getting JE?
Typically, residents of areas where JE is common, as well as travelers and deployed Service Members with extensive outdoor exposure in rural areas. Military personnel requiring immunization include: designated special-operation units; Navy mobile construction battalions; Marine expeditionary units operating in the Western Pacific; and troops assigned or deploying to Okinawa where extended field exposure is likely. For other travelers, immunize those who will spend one month or longer in rural areas, such as where rice cultivation or pig farming is common. Under normal circumstances, personnel stationed in Korea do not require immunization.

Symptoms

1) What are the symptoms of JE?
Most infections cause no symptoms. Mild infections cause a fever with headache. Severe infection develops rapidly, and causes severe headache, high fever, neck stiffness, disorientation, tremors, seizures (especially in infants), spastic paralysis and coma. Severe disease is deadly in 25% of infections.

2) How is JE treated?
Therapy for symptomatic Japanese encephalitis virus (JEV) infection is supportive. Patients often require feeding, airway management, and anticonvulsants for seizure control. No clearly effective antiviral agents exist.

Complications

1) What are some specific complications of JE?
About half of the people who survive serious JE infection are left with neurologic and psychological disabilities including behavior disorders, mental retardation, and seizures.

Vaccine

Overview

1) Is there a vaccine to prevent Japanese encephalitis (JE)?
Yes. IXIARO® has been licensed in the U.S. since March 2009 and is manufactured in the United Kingdom by Intercell Biomedical. IXIARO® is used for active immunization against JE in people 17 years of age and older who are planning to travel to areas where JE is common and laboratory personnel who work with JEV.

Administration

1) How is JE vaccine administered?
IXIARO® is an inactivated virus vaccine injected intramuscularly in a two-dose series. Doses are administered on day zero (the day of initial immunization) and on day twenty-eight. All patients receive 0.5 mL per dose. The IXIARO® series should be completed at least 1 week prior to potential exposure to JEV. The need for and timing of booster doses is not known at this time.

You cannot use IXIARO® as a booster dose for previously administered JE-Vax®. Explain to the patient that their previous doses of JE-Vax® are void and they will have to complete the two dose series of IXIARO® administration for protection against JE.

2) What are the most common side effects following JE immunizations?
The most common side effects are headache, muscle pain and injection site reactions (e.g., pain, swelling, tenderness, redness). Nausea, skin rash, fatigue, flu-like illness, and fever may also occur. Contact your health care provider if you have any of the following problems because these may be signs of an allergic reaction:

- difficulty breathing
- hoarseness or wheezing
- hives
- dizziness, weakness or fast heart beat

Contraindications

1) Who should not receive the JE vaccines?
Tell your doctor if you have any severe allergies. People who have had a severe reaction or developed a severe allergic reaction to a previous dose of JE-Vax® or IXIARO® should not be revaccinated.

Pregnant women should generally not receive JE vaccine. Check with your doctor since it could be recommended under certain circumstances.

If you will be traveling for fewer than 30 days, especially if you will be staying in major urban areas, tell your doctor. You may be at lower risk and not need the vaccine.

Anyone who has a life-threatening allergy to any component of IXIARO® should not get the vaccine. IXIARO® contains protamine sulfate, known to cause hypersensitivity reactions in some individuals. Safety and effectiveness of IXIARO® has not yet been established in pregnant women or nursing mothers.

You should tell your health care provider if you:

- have had an allergic reaction after a previous dose of JE-Vax® or IXIARO®.
- Have a bleeding disorder or a reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia) and cannot receive injections in the arm.
- have a weakened immune system, for example, due to a genetic defect or HIV infection.
- are or may be pregnant, or are breast feeding.
- currently have any illness with a fever of more than 100°F (37.8°C).
- take any medicines, even those you can buy over the counter.

2) What other precautions should be considered before administration of JE vaccines?
People with multiple allergies, especially those with a history of allergic urticaria (hives), are at higher risk for allergic complications after JE immunization. Under normal circumstances, those immunized should not travel internationally within 10 days of immunization because of the possibility of delayed allergic reactions that may require medical attention. At this time no other precautions are recommended for IXIARO®.

Special Considerations

1) Are there special restrictions for those on flight status?
Temporary flying restrictions are per Service specific policy.

2) What can I do for my pediatric child traveling to JE endemic areas?
Currently the safety and effectiveness of IXIARO® for the pediatric population has not been established. The FDA has ongoing studies, the FDA-approved IXIARO® is only for use in patients 17 years of age or older.

JE-VAX®, the only vaccine for those younger than 17 years of age, is no longer available. ACIP guidelines suggest the following options for obtaining JE vaccine for U.S. children deemed at risk for JE exposure.

a. Enroll children in the ongoing clinical trial. The ongoing pediatric safety and immunogenicity trial with IXIARO® is enrolling children aged 2 months to 17 years of age (trial identifier NCT01047839). The study is open-label, and all enrollees receive two (2) doses of IXIARO® administered 28 days apart. A third study visit is required 56 days after the first dose. Additional information about the clinical trial is available online from the National Institutes of Health at http://clinicaltrials.gov/ct2/show/nct01047839.
b. Administer IXIARO® off-label. A health-care provider may choose to administer the vaccine off-label in children aged <17 years. Additional information about the use of IXIARO® in children is available from Novartis Medical Communications by telephone (877-683-4732) or e-mail (vaccineinfo.us@novartis.com).