

DEPARTMENT OF THE AIR FORCE HEADQUARTERS UNITED STATES AIR FORCE WASHINGTON DC

9 January 2015

MEMORANDUM FOR AFMOA/CC MAJCOM/SGs

FROM: AF/SG

SUBJECT: Guidance on the use of Japanese Encephalitis Vaccine

Japanese encephalitis (JE) is a rare disease which causes death or permanent neurologic sequelae in up to 50% of people who are diagnosed. The risk of disease is low, but is variable and unpredictable. In November 2013, the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) recommended use of JE vaccine for travelers age 2 months and older who plan to spend a month or longer in endemic areas during the JE virus transmission season. The CDC and World Health Organization describe most of Asia, including the countries of Japan and the Republic of Korea (ROK) as endemic areas.

As of 1 February 2015, JE vaccine will be a required immunization for all Airmen assigned to Japan and ROK. Individuals will be identified as part of an immunization group in ASIMS and JE vaccine will appear as due on IMR lists at that time (See PACAF JE Vaccination Implementation Plan at Attachment 1). Airmen will have 12 months to accomplish the primary two-dose vaccination series before their IMR status shows as overdue (red). Airmen PCSing to Japan or ROK will be assigned to country-specific immunization groups by home station MTFs during out-processing (See Attachment 2 for guidance). Every effort should be made to complete the two-dose primary JE vaccine series before departing home station. Individuals deploying to areas in Pacific Command (PACOM) will continue to be administered JE vaccine in accordance with ACIP recommendations and PACOM Force Health Protection guidance.

Family members and other Tricare beneficiaries who are living in or PCSing to Japan and ROK are encouraged to receive JE vaccine in accordance with current ACIP recommendations. Airmen receiving JE vaccine should be given educational material to share with family members.

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Attachments: 1. PACAF JE Vaccination Implementation Plan 2. JE Vaccination Guidance



PACAF Japanese Encephalitis Vaccination Implementation Plan

November 2014

1. Purpose:

This message provides PACAF guidance for the Japanese Encephalitis vaccination program. Implementation of this plan will be carried out in accordance with OSD/HA and AF/SG policy. Request dissemination of this message to military treatment facility (MTF) commanders, immunization clinics, primary care clinics that administer immunizations, public health offices, pharmacy services, medical logistics/supply sections, and primary care managers.

2. Background:

Japanese encephalitis (JE) is a mosquito-borne virus endemic to much of the Pacific region, including the Republic of Korea and Japan. It usually occurs in rural or agricultural areas, often associated with rice farming. In temperate areas of Asia, transmission is seasonal, and human disease usually peaks in the summer and fall. In the subtropics and tropics, transmission can occur year-round, often with a peak during the rainy season. It takes 5 to 15 days after the bite of an infected mosquito to develop symptoms. Most people who are infected develop mild symptoms or no symptoms at all. In people who develop severe disease, initial symptoms include fever, chills, headache, fatigue, nausea and vomiting. The disease can progress to inflammation of the brain (encephalitis) and is often accompanied by seizures. Coma and paralysis occur in some cases. Of infected individuals, <1% develop clinical disease. Among clinically ill patients, the case-fatality rate is 20-30%. Among survivors, 30-50% have serious long term neurologic, cognitive, or psychiatric sequelae.

The Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control (CDC) has recommended vaccination against JE for all Americans who spend a month or more in Republic of Korea and Japan during the viral transmission season.

The National Center for Medical Intelligence assessment of baseline risk to US personnel in Japan and Republic of Korea is an intermediate risk with a potential attack rate of <1/1,000 per month, with the possibility of rare cases. The year-to-year risk of JE to unvaccinated personnel in Republic of Korea is unpredictable, depending on mosquito activity. Extensive childhood vaccination has greatly lowered incidence of JE in the South Korean population. However, this immunization program does not lower the risk for non-immunized U.S. personnel. The absence of reported cases in U.S. personnel does not imply lack of risk; unvaccinated personnel remain at risk every year.

Japanese encephalitis vaccine is approved for people 2 months of age and older. The vaccine is given as a 2-dose series, with the doses spaced 28 days apart. Children younger than 3 years of age get a smaller dose than patients who are 3 or older. A booster dose should be recommended for anyone 17 or older who was vaccinated more than a year ago and is still at risk of exposure.

3. Key Messages:

3.1. Your health and safety are our #1 concern.

3.2. The vaccine is safe and effective.

3.3 The threat from Japanese Encephalitis is small but real with a potential for very serious consequences.

4. Applicability and Scope:

4.1. All uniformed Air Force personnel assigned, deployed, or TDY to Japan or Republic of Korea for 30 or more consecutive days will be vaccinated against Japanese Encephalitis.

4.2. DoD civilian employees assigned, deployed, or TDY for 30 or more consecutive days to Japan or Republic of Korea are encouraged to receive the vaccine.

4.3. Command-sponsored dependents and other eligible beneficiaries spending 30 or more consecutive days in Japan or Republic of Korea are encouraged to receive the vaccine.

5. Responsibilities:

5.1. PACAF SG is the office of primary oversight for the implementation of this plan. PACAF SG will ensure adequate medical resources are planned, programmed and budgeted to support unit commanders and individuals in achieving and maintaining this Individual Medical Readiness (IMR) component.

5.2. Installation commanders will establish a command expectation that unit commanders and individuals will comply with this plan to maintain IMR.

5.3. MTF commanders will maintain adequate capabilities to ensure implementation of this plan and ensure that commanders and medical personnel are educated on the requirements and details of this plan.

5.4. Unit commanders will establish a command expectation that individuals will be personally responsible for meeting IMR requirements and ensure unit personnel are vaccinated IAW this plan.

5.5. Service members will receive the vaccine as directed. They should be encouraged to inform their dependents of the risk of JE and provide opportunities for vaccination.

6. Education Plan: Education is the key to a successful vaccination program. Commanders at all levels are responsible for briefing their personnel on this IMR requirement.

6.1. MTF commanders (or designated representative) will brief commanders and medical personnel about consequences of JE disease, vaccine requirements, and local implementation of this plan.

6.2. Medical personnel are the primary sources of information on the disease, the vaccine and vaccine side effects. They must be familiar with JE and JE vaccination in order to educate unvaccinated beneficiaries on this disease and encourage widespread vaccination.

6.3. Community Education. Installation medical officials will provide disease talking points and key messages to Public Affairs for editing and public dissemination preparation. Health officials and Public Affairs personnel will coordinate on appropriate dissemination mediums (social media, websites, base newspaper, Commander's Access Channel, AFN, etc.) to educate beneficiaries on JE transmission, disease, consequences, and vaccination. Medical officials will provide their subject matter expertise on content of messaging while PA will focus on formatting, editing and dissemination tactics.

7. Medical Issues:

7.1. Dosing schedule. IXIARO (Japanese Encephalitis Vaccine, Inactivated, Adsorbed) is supplied in 0.5mL single dose syringes. The primary series for individuals 3 years of age and older is two 0.5mL doses administered 28 days apart. For children ages 2 months up to 3 years of age the primary series is two 0.25 mL doses 28 days apart. Consult the package insert for preparation of a 0.25 mL dose. Doses must be administered at least 28 days apart. If the interval between doses is extended there is no need to restart the series.

7.2. Administration. IXIARO is administered intramuscularly. The preferred sites for intramuscular injection are the anterolateral aspect of the thigh in infants 2 to 11 months of age, the anterolateral aspect of the thigh (or the deltoid muscle if muscle mass is adequate) in children 1 to <3 years of age, or the deltoid muscle in individuals 3 years of age and older. Do not administer intravenously, intradermally, or subcutaneously. Shake the syringe well to obtain a white, homogeneous suspension prior to administration.

7.2.1. Dose: Individuals 17 years of age and older: If the primary series of two doses of IXIARO was completed more than 1 year previously, a booster dose should be given if ongoing exposure or re-exposure to JE is expected.

7.2.2. Previous vaccination against JE. Individuals 17 years of age or older who have received JE-MB (inactivated virus grown in mouse brain-MB) previously (this vaccine has not been available since 2011) will receive a 2-dose primary series of IXIARO and booster if indicated at one year (there are no data on the effectiveness of IXIARO as a booster dose after JE-MB).

7.3. Adverse Reactions. Common vaccine side effects include pain, tenderness, and redness at the injection site; headache, muscle pain; fatigue; and low grade fever. All vaccine-related adverse events must be reported through the Vaccine Adverse Event Reporting System (VAERS). Additionally, health-care professionals should promptly report all clinically

significant adverse events after vaccination of children, even if the health care professional is not certain the vaccine caused the event. The VAERS form is available in the Aeromedical Services Information Management System (ASIMS) or at: <u>http://vaers.hhs.gov/esub/index</u>.

7.4. Pregnancy. Pregnant women should delay vaccination until after pregnancy. IXIARO is classified as pregnancy category B (animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women).

7.5. Contraindications. Anyone who has had a severe (life-threatening) allergic reaction to a dose of JE vaccine or any component of the vaccine (including protamine sulfate) should not receive another dose.

7.6. Aeromedical Impact. Inoculation with IXIARO does not require an extended DNIF period and aeromedical dispositions should be handled in concert with administration of any other immunization as identified in the Aircrew Medications list (access to medical care on the ground is recommended for a period of 4 hours for all personnel, unless operational needs dictate otherwise).

7.7. Medical Exemptions. There are two types of medical exemptions-temporary and permanent.

7.7.1. Temporary medical exemptions are indicated in situations where it is clinically inappropriate to administer the vaccine to an individual due to a condition that is expected to resolve or otherwise end. Examples include immunosuppressive therapy, serious acute diseases, post-surgical situations, pregnancy, and in some situations where a medical condition is being evaluated or treated. This would include significant vaccine-associated adverse events that are being evaluated, or while awaiting specialist consultation. Temporary medical exemptions may be granted by any privileged military health care provider or based on the examination of a civilian provider. Temporary exemptions cannot exceed 365 days, and should be limited to the shortest duration necessary.

7.7.2. Permanent medical exemptions are generally warranted if the medical condition or adverse reaction is so severe that the risk of continued immunization is not justified. An example of a situation that warrants a permanent medical exemption is a severe reaction after a previous JE vaccination such that additional doses would pose an undue risk to the vaccine recipient.

7.8. Tracking and Documentation. All vaccinations will be documented in ASIMS, at the point of service (POS) if possible. If POS electronic documentation is not possible, ASIMS will be updated no later than the next duty day. Records of individuals subject to mandatory vaccination who are identified as "due" for next dose will turn yellow in ASIMS and show on the unit's IMR Due and Overdue Report. If the individual does not receive the vaccination during the "due" grace period, the individual's record will become "overdue" and turn red in ASIMS. This will affect the unit's IMR rate.

7.9. Vaccine Information Statement (VIS). IAW U.S. Code 42, the current VIS on JE vaccine, published by the CDC, shall be provided to any individual receiving a vaccine or, in the case

of children, to the child's legal representative (i.e., parents or guardians). Additionally, reasonable effort to ensure the patient or legal representative understands the material presented is expected. The VIS for JE is available at http://www.cdc.gov/vaccines/hcp/vis/vis-statements/je-ixiaro.pdf.

7.10. Storage and Handling. Store vaccine in a refrigerator at 2° to 8° C (35° to 46° F). Do not freeze.

8. Implementation Timeline:

8.1. ASIMS will be updated to comply with this requirement. For personnel permanently assigned to a Japan or Republic of Korea location, JE will appear as yellow on the IMR list as of 1 Jan 2015. Personnel will have 365 days to complete the two-shot series. If they have not completed the series within 365 days, their IMR status will turn red. Every effort should be made to vaccinate personnel PCSing to Japan or Republic of Korea prior to their arrival.

8.2. Uniformed personnel deploying or TDY to Japan or Republic of Korea for 30 or more consecutive days will be vaccinated at their home station. DoD civilian employees deploying or TDY to Japan or Republic of Korea for 30 or more consecutive days are encouraged to receive the vaccine. Every effort should be made to provide both doses prior to deployment or TDY.

8.3. Begin immunizing as soon as vaccine becomes available.

9. Waivers and Exemptions:

9.1. Religious Waivers. Guidance for religious waivers can be found in AFI 48-110, Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases. IAW this AFI, the Air Force does not grant permanent immunization exemptions for religious reasons. COMPACAF is the approval and revocation authority for temporary exemptions.

9.2. Administrative Exemptions. Personnel who are separating or retiring within 90 days can be exempted from vaccination. Personnel who are PCSing from Republic of Korea or Japan within 90 days can be exempted from vaccination provided they are not moving to another Republic of Korea or Japan installation.

9.3. Medical Exemptions. Medical exemptions may be temporary or permanent and may be based on pre-existing conditions or result from vaccine adverse reactions. See section 7.7. of this plan.

References:

AFI 48-110 IP, Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases. 7 Oct 2013.

Guidance on the use of Japanese Encephalitis Vaccine. Dr. Woodson ASD/HA, May 07 2013.

Aircrew Medications List. Current version available on the AFMS KX Flight Medicine Branch page: https://kx2.afms.mil/kj/kx4/FlightMedicine/Pages/home.aspx

Japanese Encephalitis Vaccines Recommendations of the Advisory Committee on Immunization Practices (ACIP). Morbidity and Mortality Weekly Report March 12, 2010 / Vol. 59 / No. RR-1.

Use of Japanese Encephalitis Vaccine in Children: Recommendations of the Advisory Committee on Immunization Practices, 2013. MMWR / November 15, 2013 / Vol. 62 / No. 45.

IXIARO Package Insert https://www.novartisvaccinesdirect.com/Pdf/Ixiaro_PI.pdf

IXIARO Vaccine Information Statement <u>http://www.cdc.gov/vaccines/hcp/vis/vis-statements/je-ixiaro.pdf</u>

Attachment 2

Japanese Encephalitis (JE) Vaccination Implementation Guidance for MTFs Located Outside Japan and the Republic of Korea

- 1. As of 1 January 2015, USAF will mandate Japanese Encephalitis (JE) vaccination for all Air Force uniformed personnel, who are assigned, deployed, or TDY to Japan or the Republic of Korea (ROK) for 30 or more consecutive days. DoD civilian employees and command-sponsored dependents and other eligible beneficiaries spending 30 or more consecutive days in Japan or ROK are encouraged to receive JE vaccine. This document provides additional guidance to MTFs in support of the PACAF JE Vaccination Implementation Plan.
 - a. To prepare for implementation, PACAF has notified AFPC of the impending JE vaccination requirement for PCS to Japan or ROK and has requested Personnel Processing Codes (PPC) identifying that requirement.
 - b. PACAF personnel will update requirements in the ASIMS deployment module for Japan and ROK to identify the JE vaccination requirement on 1 January, 2015.
 Pre-deployment medical clearance will then require JE vaccination for military deployers, and civilian deployers will be highly encouraged to receive JE vaccine.
- 2. MTF Commanders will ensure the following is accomplished in support of the PACAF JE vaccination requirement:
 - a. Ensure appropriate MTF staff are educated on JE disease, the benefits of vaccination, and the requirement and/or recommendation for JE vaccination for individuals as defined in item 1 above. Medical personnel must be familiar with this information in order to educate beneficiaries on this disease and encourage widespread vaccination of those moving to Japan or ROK. At a minimum, this education should be provided to Immunization and Flight Medicine Clinic personnel and primary care physicians. Preventive medicine and/or public health personnel can provide this education.
 - b. Ensure logistics personnel are educated on this new immunization requirement and plan for JE vaccine supply based on local needs.
 - c. Ensure responsible MTF staff comply with requirements listed in items 3 and 4 below.
- 3. Identification of JE vaccination requirement for personnel stationed at MTFs outside Japan or ROK:
 - a. PPCs for ROK and Japan will be updated to reflect the requirement for JE vaccination for PCS. The PPC states that medical requirements must be met prior to publishing orders.
 - b. ASIMS immunization groups will be updated to comply with this requirement. When individuals report to the Immunization Clinic, Flight Medicine Clinic, or Public Health office at the losing base for clearance prior to PCS, personnel will ensure that individual is assigned to the appropriate immunization group in ASIMS to identify the JE vaccine requirement. Once assigned to the appropriate immunization group, the due date for the second dose in the primary series will be automatically identified in ASIMS.

1) Individuals PCSing to Japan will be assigned to the "PCS Japan" immunization group.

2) Individuals PCSing to ROK will be assigned to the "PCS Korea" immunization group.

- c. Public Health, Immunization Clinic, and/or Flight Medicine Clinic personnel will provide educational materials to the PCSing individual to share with family members who will be accompanying them to Japan or ROK. These educational materials are being developed in collaboration with the Defense Health Agency Immunization Healthcare Branch and will be distributed to the MTFs when available. Until these items are available, the JE Vaccine Information Statement (VIS) and additional information found at the following Center for Disease Control website are good sources for educational material: http://www.cdc.gov/japaneseencephalitis/qa/index.html
- 4. Medical Issues related to provision of JE vaccine:
 - a. Dosing schedule. IXIARO (Japanese Encephalitis Vaccine, Inactivated, Adsorbed) is supplied in 0.5mL single dose syringes. The primary series for individuals 3 years of age and older is two 0.5mL doses administered 28 days apart. For children ages 2 months up to 3 years of age the primary series is two 0.25 mL doses 28 days apart. Consult the package insert for preparation of a 0.25 mL dose. Doses must be administered at least 28 days apart. If the interval between doses is extended there is no need to restart the series.
 - b. Administration. IXIARO is administered intramuscularly. The preferred sites for intramuscular injection are the anterolateral aspect of the thigh in infants 2 to 11 months of age, the anterolateral aspect of the thigh (or the deltoid muscle if muscle mass is adequate) in children 1 to <3 years of age, or the deltoid muscle in individuals 3 years of age and older. Do not administer intravenously, intradermally, or subcutaneously. Shake the syringe well to obtain a white, homogeneous suspension prior to administration.</p>
 - c. Booster Dose. Individuals 17 years of age and older: If the individual who is PCSing to Japan or ROK received the primary series of two doses of IXIARO more than 1 year previously, a booster dose must be given prior to departing home station.
 - d. Previous vaccination against JE. Individuals 17 years of age or older who have received JE-MB (inactivated virus grown in mouse brain-MB) previously (this vaccine has not been available since 2011) will receive a 2-dose primary series of IXIARO and booster if indicated at one year (there are no data on the effectiveness of IXIARO as a booster dose after JE-MB).
 - e. Adverse Reactions. Common vaccine side effects include pain, tenderness, and redness at the injection site; headache, muscle pain; fatigue; and low grade fever. All vaccine-related adverse events must be reported through the Vaccine Adverse Event Reporting System (VAERS). Additionally, health-care professionals should promptly report all clinically significant adverse events after vaccination of children, even if the health care professional is not certain the vaccine caused the event. The VAERS form is available in the Aeromedical

Services Information Management System (ASIMS) or at: <u>http://vaers.hhs.gov/esub/index</u>.

- f. Pregnancy. Pregnant women should delay vaccination until after pregnancy. IXIARO is classified as pregnancy category B (animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and wellcontrolled studies in pregnant women).
- g. Contraindications. Anyone who has had a severe (life-threatening) allergic reaction to a dose of JE vaccine or any component of the vaccine (including protamine sulfate) should not receive another dose.
- Aeromedical Impact. Inoculation with IXIARO does not require an extended DNIF period and aeromedical dispositions should be handled in concert with administration of any other immunization as identified in the Aircrew Medications list (access to medical care on the ground is recommended for a period of 4 hours for all personnel, unless operational needs dictate otherwise).
- i. Medical Exemptions. There are two types of medical exemptions--temporary and permanent.

1) Temporary medical exemptions are indicated in situations where it is clinically inappropriate to administer the vaccine to an individual due to a condition that is expected to resolve or otherwise end. Examples include immunosuppressive therapy, serious acute diseases, post-surgical situations, pregnancy, and in some situations where a medical condition is being evaluated or treated. This would include significant vaccine-associated adverse events that are being evaluated, or while awaiting specialist consultation. Temporary medical exemptions may be granted by any privileged military health care provider or based on the examination of a civilian provider. Temporary exemptions cannot exceed 365 days, and should be limited to the shortest duration necessary.

2) Permanent medical exemptions are generally warranted if the medical condition or adverse reaction is so severe that the risk of continued immunization is not justified. An example of a situation that warrants a permanent medical exemption is a severe reaction after a previous JE vaccination such that additional doses would pose an undue risk to the vaccine recipient.

- j. Tracking and Documentation. All vaccinations will be documented in ASIMS, at the point of service (POS) if possible. If POS electronic documentation is not possible, ASIMS will be updated no later than the next duty day.
- k. Vaccine Information Statement (VIS). IAW U.S. Code 42, the current VIS on JE vaccine, published by the CDC, shall be provided to any individual receiving a vaccine or, in the case of children, to the child's legal representative (i.e., parents or guardians). Additionally, reasonable effort to ensure the patient or legal representative understands the material presented is expected. The VIS for JE is available at <u>http://www.cdc.gov/vaccines/hcp/vis/vis-statements/je-ixiaro.pdf.</u>
- 1. Storage and Handling. Store vaccine in a refrigerator at 2° to 8° C (35° to 46° F). Do not freeze.

References:

AFI 48-110 IP, Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases. 7 Oct 2013.

Guidance on the use of Japanese Encephalitis Vaccine. Dr. Woodson ASD/HA, May 07 2013.

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Use of Japanese Encephalitis Vaccine in Children: Recommendations of the Advisory Committee on Immunization Practices, 2013. MMWR / November 15, 2013 / Vol. 62 / No. 45.

IXIARO Package Insert https://www.novartisvaccinesdirect.com/Pdf/Ixiaro_PI.pdf

IXIARO Vaccine Information Statement <u>http://www.cdc.gov/vaccines/hcp/vis/vis-statements/je-ixiaro.pdf</u>