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IN REPLY REFER TO

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From: Chief, Bureau of Medicine and Surgery
To: All Navy Medicine Activities

Subj: JAPANESE ENCEPHALITIS VACCINE

Encl: (1) COMPACFLT Japanese Encephalitis (JE) Vaccination Implementation Plan

1. Japanese encephalitis (JE) is a rare viral infection spread by *Culex* mosquitoes that feed in the evening and throughout the night. Most persons infected with the JE virus have no symptoms or experience a mild non-specific cold or flu-like illness (>99%). A small percentage of those infected (<1%) develop a more severe form of the disease in which significant temporary and potentially permanent neurological deficits may occur.
2. The disease is endemic throughout the Commander, U.S. Pacific Fleet area of responsibility, including Japan and the Korean peninsula. The Centers for Disease Control and Prevention Advisory Committee on Immunization Practices currently recommends the use of the two-dose JE vaccine (IXIARO) for travelers age 2 months and older who plan to spend 30 days or longer in endemic areas during virus transmission periods or will be at an increased risk for any time period of travel to rural areas in endemic countries.
3. As of 1 November 2016, JE vaccination became an Individual Medical Readiness requirement for all Navy and Marine Corps Service members stationed, deployed, or on temporary additional duty orders (ashore or afloat) to Japan or the Republic of Korea for 30 or more consecutive days. Every effort should be made to complete the vaccination series prior to arrival. Refer to enclosure (1) for detailed information regarding the implementation of this requirement.
4. Command-sponsored dependents and other eligible beneficiaries spending 30 or more consecutive days in Japan or the Republic of Korea are recommended to receive the vaccination series per Advisory Committee on Immunization Practices recommendations.
5. The U.S. Pacific Fleet (N01H) point of contact is CDR George Coan, george.coan@navy.mil.


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Japanese Encephalitis Virus Fact Sheet for the Provider

Background

Japanese encephalitis (JE) is a viral infection spread by *Culex* mosquitoes that feed in the evening and throughout the night. Originally discovered in Japan, it is a common disease in East Asia (Japan, Korea, China), South Asia (India), and the island countries of the Western Pacific (Indonesia, Philippines, Papua New Guinea). Exposure to JE infected mosquitoes most commonly occurs in rural areas with rice cultivation and pig farming.

Clinical Characteristics

Most people infected with the JE virus have no symptoms or experience a mild non-specific cold or flu-like illness (>99%). A small percentage of those infected (<1%) develop a more severe form of the disease in which significant neurological symptoms such as muscle weakness, paralysis, seizure, and altered consciousness may occur. Approximately 30-50% of these patients experience various permanent neurological deficits.

Transmission

Transmission occurs from the bite of an infected *Culex* mosquito. These mosquitoes feed primarily in the evening and throughout the night. Wading birds and pigs are believed to be the primary reservoir for the virus. People become infected after a mosquito bites an infected bird or pig and then bites a human for a second feeding. The estimated incidence of the more severe form of the disease among travelers to Asia is <1 case per 1 million travelers. Risk is higher in persons with a longer duration of travel (>30days) or in those who have extensive outdoor activities in rural areas.

Prevention

The best method to prevent JE is to prevent or minimize mosquito bites. Force protection efforts should be maintained to ensure that personnel are supplied and educated on the use of appropriate PPE (25-30% DEET containing insect repellent on exposed skin, wearing permethrin treated uniforms, and sleeping inside bed nets or within screened or air-conditioned enclosures). However, protection from JE can be increased with the use of the JE vaccine that is available via a two-dose series. COMPACFLT has recently released a JE vaccination policy message (DTG 102140Z NOV 16) that mandates that all Navy and Marine Corps personnel assigned to operations in Japan or the Korean peninsula for 30 days or longer complete the JE vaccination series prior their arrival in theater. A risk-based assessment is recommended for personnel operating in other countries within the Pacific Fleet AOR or for those with operations in Japan or the Korean peninsula of less than 30 days. This policy change aligns COMPACFLT JE force protection policy with current Air Force, Marine Corps, and Army policies in Japan and the Korean peninsula.



COMPACFLT
JAPANESE ENCEPHALITIS (JE) VACCINATION
IMPLEMENTATION PLAN

MARCH 2017

1. Purpose.

To establish an implementation plan for the Commander, U.S. Pacific Fleet (COMPACFLT) Japanese Encephalitis Vaccination program. Execution will be carried out in accordance with the Assistant Secretary of Defense for Health Affairs (ASD(HA)) and Navy Bureau of Medicine and Surgery (BUMED) Surgeon General (SG) Japanese Encephalitis Vaccination policies. Request dissemination of this plan to all Military Treatment Facility (MTF) Commanding Officers (CO's), immunization clinics, primary care clinics that administer immunizations, travel medicine clinics, pharmacies, medical logistics/supply sections, and primary care managers.

2. Background.

Japanese encephalitis (JE) is an arboviral disease transmitted by *Culex* mosquitoes. It is endemic throughout the COMPACFLT area of responsibility (AOR), including Japan and the Republic of Korea. The disease most frequently occurs in persons living in rural or agricultural areas associated with rice or pig 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 peaking during the rainy season. It takes 5 to 15 days after the bite of an infected mosquito for a person to develop symptoms. Most individuals infected with JE are asymptomatic or experience only a mild illness (>99%). In individuals who develop severe disease (<1%), initial symptoms include fever, chills, headache, fatigue, nausea and vomiting. In these patients the disease can progress to inflammation of the brain (encephalitis) with possible seizure, coma, paralysis, and death. Persons who develop encephalitis are at a high risk of short- and long-term neurologic morbidity and mortality (~50%). There is no specific treatment for infected individuals.

The Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control (CDC) has recommended vaccination against JE for all persons who spend greater than 30 days in Japan and/or the Republic of Korea during the viral transmission season. These recommendations are available at <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/je.html>

The National Center for Medical Intelligence (NCMI) assessment of baseline risk to U.S. military personnel in Japan and the Republic of Korea is intermediate with a potential attack rate of <1/1,000 per month. The year-to-year risk of JE to

unvaccinated personnel in the Republic of Korea is unpredictable, depending on mosquito activity. Extensive childhood vaccination has greatly lowered the incidence of JE in the Republic of Korea. 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.

In the U.S. the only Food and Drug Administration (FDA) approved vaccine for JE prevention is IXIARO manufactured by Valneva. It is given in a two-dose series on days zero and 28 days. The initial vaccine series is approved for individuals 2 months of age and older. A one-year booster dose is recommended for individuals aged 17 years and older with continued risk.

3. Key Messages.

a. The health, safety and welfare of each sailor, Department of Defense (DoD) civilian employee and dependent are the top priority of COMPACFLT.

b. The vaccine is safe and effective.

c. The threat from Japanese Encephalitis is small, but real, with the potential for very serious consequences.

4. Applicability and Scope.

a. All Navy and Marine Corps service members stationed, deployed, or on Temporarily Additional Duty (TAD) orders (ashore or afloat) to Japan or the Republic of Korea for 30 or more consecutive days will be vaccinated to against JE.

b. DoD civilian employees stationed, deployed, or on TAD orders for 30 or more consecutive days to Japan or the Republic of Korea are highly encouraged to receive the vaccination series.

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

5. Responsibilities.

a. COMPACFLT N01H (Force Surgeon) and BUMED SG have primary oversight for the implementation of this plan.

b. COMPACFLT N1 (Total Fleet Force and Personnel) will insert a JE vaccination requirement in all Official Orders for Navy and Marine Corps service members executing a Permanent Change of Station (PCS) or other duty assignment to Japan or the Republic of Korea for 30 or more consecutive days.

c. Installation CO's will establish a command expectation that unit CO's and service members will comply with this plan to maintain IMR.

d. MTF CO's 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.

e. Unit CO's will establish a command expectation that service members will be personally responsible for meeting IMR requirements and ensure unit personnel are vaccinated in accordance with (IAW) this plan.

f. Service members will receive the vaccination series 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.

a. MTF CO's (or designated representative) will brief unit CO's and their medical personnel about consequences of JE disease, vaccination requirements, and local implementation of this plan.

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

c. Community Education. Installation medical officials will provide disease talking points and key messages to Public Affairs (PA) for editing and public dissemination preparation. Medical officials and PA personnel will coordinate on appropriate dissemination mediums (social media, websites, base newspaper, Armed Forces Network (AFN), etc.) to educate beneficiaries on JE transmission, disease, consequences, and

vaccination. Medical officials will provide subject matter expertise on content of messaging, while PA will focus on formatting, editing and dissemination tactics.

d. Educational guidance handouts for providers and patients on JE are provided in Enclosures (1) and (2).

e. Force Health Protection (FHP) Guidance. U.S. Pacific Command (USPACOM) FHP Guidance for Navy and Marine Corps service members stationed, deployed, or on Temporarily Additional Duty (TAD) orders (ashore or afloat) to Japan or the Republic of Korea for 30 or more consecutive days will be updated to reflect readiness changes directed as part of this implementation plan.

7. Medical Issues.

a. Dosing schedule. IXIARO (Japanese Encephalitis Vaccine, Inactivated, Adsorbed) is supplied in 0.5mL single dose syringes.

(1) The primary series for individuals 3 years of age and older is two 0.5mL doses administered 28 days apart.

(2) 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.

(3) 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.

(1) Booster Dose. For individuals 17 years of age and older, if the primary series of two doses of IXIARO was completed more than 1 year previously, a one-time booster dose should be given if ongoing exposure or re-exposure to JE is expected.

(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 the two-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).

c. 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 at: <http://vaers.hhs.gov/esub/index>.

d. Pregnancy. In general pregnant women should delay vaccination until after pregnancy unless there is a high risk of exposure. IXIARO is classified by the FDA as pregnancy category B. Adverse events were not observed in animal reproduction studies. Infection from JE during the first or second trimesters of pregnancy may increase risk of miscarriage. Intrauterine transmission of the JE virus has been reported by the CDC in 2010.

e. 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 vaccination.

f. 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 (e.g. anaphylaxis).

g. Tracking and Documentation. All vaccinations will be documented in the Armed Forces Longitudinal Technology Application (AHLTA) or the Theater Medical Information Program - Maritime (TMIP-M), and the Medical Readiness Reporting System (MRRS), at the point of service, when possible. If electronic vaccination documentation is not possible at time of administration, AHLTA or TMIP-M, and MRRS will be updated no later than the next duty day.

(1) On and after 28 days from receiving the first dose, records of service members subject to mandatory vaccination will be identified as "due" and the service member's status will turn "yellow" in MRRS to show the service member as "due" on the unit's "IMR Due and Overdue Report".

(2) If the service member does not receive the second vaccination during the "due" grace period (365 days), the service member's record will become "overdue" and status will turn "red" in MRRS. This status change will also affect the unit's overall IMR rate.

h. Vaccine Information Statement (VIS). IAW U.S. Code 42, the current VIS on JE vaccine, published by the Centers for Disease Control and Prevention (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 the JE vaccine is available at <https://www.cdc.gov/vaccines/hcp/vis/vis-statements/je-ixiaro.html>

i. Storage and Handling. Store the vaccine in a refrigerator specifically designated for storage of medications or vaccinations at 2° to 8° C (35° to 46° F). Do not freeze.

8. Implementation Timeline.

a. Implementation Date. As per COMPACFLT Message (DTG 102140Z NOV 16) titled "Guidance on the Japanese Encephalitis Vaccine for U.S. Navy Personnel and TRICARE beneficiaries in the Pacific Fleet Area of Responsibility," the implementation plan is set.

b. MRRS will be updated to comply with this requirement. Upon implementation of this plan, Navy and Marine Corps service members permanently assigned to a duty station (ashore or afloat) located in Japan or the Republic of Korea location will appear as "yellow" on the IMR list.

(1) Personnel will have 365 days to complete the two-shot series. If the service member fails to complete the series within 365 days, the service member's IMR status will turn "red".

(2) Every effort should be made to complete the vaccination series for personnel on PCS orders to Japan or the Republic of Korea prior to arrival in the AOR.

c. Navy and Marine Corps service members deploying or on TAD orders to Japan or the Republic of Korea for 30 or more consecutive days will be vaccinated at their home station. Every effort should be made to provide both doses prior to deployment or TAD.

d. DoD civilian employees deploying or on TAD orders to Japan or the 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 TAD.

e. Immunization shall begin as soon as the vaccine becomes available.

9. Waivers and Exemptions.

a. Religious Waivers. Guidance for religious waivers can be found in BUMEDINST 6230.15B, Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases. IAW this instruction, the Navy does not grant permanent immunization exemptions for religious reasons. COMPACFLT N01H is the approval and revocation authority for temporary exemptions.

b. Administrative Exemptions. Personnel who are separating or retiring within 90 days can be exempted from vaccination. Personnel with PCS orders from the Republic of Korea or Japan within 90 days can be exempted from vaccination provided they are not moving to another installation in Japan or the Republic of Korea.

c. 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.f. of this plan.

Enclosures

- (1) NEPMU-6 Japanese Encephalitis Virus Fact Sheet for the Provider, March 2017
- (2) NEPMU-6 Japanese Encephalitis Virus Fact Sheet for the Patient, March 2017

References

- (a) BUMEDINST 6230.15B , Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases. 7 Oct 2013.
- (b) COMPACFLT PEARL HARBOR HI MSG DTG 102140Z NOV 16, Guidance on the Japanese Encephalitis Vaccine for U.S. Navy Personnel and TRICARE beneficiaries in the Pacific Fleet Area of Responsibility
- (c) Guidance on the use of Japanese Encephalitis Vaccine. Dr. Woodson ASD/HA, May 7 2013
- (d) Japanese Encephalitis Advisory Committee on Immunization Practices (ACIP) Vaccine Recommendations, <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/je.html>
- (e) Japanese Encephalitis Vaccines Recommendations of the Advisory Committee on Immunization Practices (ACIP) Morbidity and Mortality Weekly Report (MMWR), March 12, 2010 / Vol. 59 / No. RR-1
- (f) Use of Japanese Encephalitis Vaccine in Children: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2013. Morbidity and Mortality Weekly Report (MMWR), November 15, 2013 / Vol. 62 / No. 45

- (g) IXIARO Package Insert, <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142569.pdf>
- (h) IXIARO Vaccine Information Statement, <https://www.cdc.gov/vaccines/hcp/vis/vis-statements/je-ixiaro.html>