

## Model Immunization Protocol

<b>Japanese Encephalitis Vaccine (Ixiaro®)</b>	
Last Reviewed	April 21, 2020
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### 1. What’s new

Incorporation of an expedited series for adults aged 18–65 years. For adults in this age range, the second dose may be given 7 or more days after dose 1.

## 2. Oregon model immunization protocol:

- A. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.
- B. Screen clients  $\geq 2$  months of age for contraindications and precautions.
- C. Provide a current VIS, answering any questions.
- D. Record all required data elements in the client's permanent health record.
- E. Verify needle length for IM injection into the vastus lateralis or deltoid muscles.
- F. Avoid injecting in the upper third of the deltoid muscle.
- G. Both client and vaccinator must be seated for vaccine administration.
- H. See section package insert page 3–4 for administration of **IXIARO**<sup>®</sup>.
- I. Give **IXIARO**<sup>®</sup> intramuscularly (**IM**) according to age and dose volume. See section 3 for schedule.
- J. This vaccine may be given with all ACIP–recommended child and adult vaccinations.
- K. Ask client to remain seated on the premises for 15 minutes after vaccination to decrease the risk of injury should they faint.

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Health Officer Signature

Date

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Health Officer Signature

Date

### 3. Vaccine schedule for Japanese Encephalitis

IXIARO <sup>®1</sup> (JE-VC)				
Age	Dose in Series	Acceptable age range	Dose Volume	Booster
2–35 months	2 doses at 0 and 28 days	≥2 months of age	0.25mL	≥1 year after primary series*
3 – 17 years	2 doses at 0 and 28 days	≥3 years	0.5mL	
18-65 years	2 doses at 0 and ≥7 days			
≥ 65 years	2 doses at 0 and 28 days			

\*If ongoing exposure or re-exposure to JE virus is expected.<sup>3</sup>

### 4. Licensed vaccine<sup>1</sup>

Product Name	Vaccine Components	Acceptable Age Range	Dose Volume	Booster Dose	Thimerosal
IXIARO <sup>®</sup> (JE-VC)	6 antigen units purified, inactivated JEV proteins and 250 µg of aluminum hydroxide per 0.5-mL dose	2 months–2 years of age	0.25 mL**		No
		3–16 years of age	0.5 mL		
		≥17 years of age	0.5 mL	≥1 year after primary series*	

\*If ongoing exposure or re-exposure to JE virus is expected.<sup>3</sup>

\*\*To administer a 0.25-mL dose, expel and discard half of the volume from the 0.5-mL prefilled syringe.<sup>1</sup>

## 5. Recommendations for use<sup>3</sup>

### A. Japanese Encephalitis vaccination is recommended for the following:

1. Persons moving to JE-endemic countries.
2. Travelers who plan to spend a month or longer in endemic areas.
3. Laboratory personnel who work with live, wild-type JEV strains.<sup>2</sup>

### B. Booster doses

1. A booster dose should be given  $\geq 1$  year after completion of the primary JE-VC series if ongoing exposure or reexposure to JE virus is expected.
2. The 2-dose primary series of JE-VC vaccine should be given to persons who received JE-MB (JE-VAX<sup>®</sup>) and need a booster.
3. Vaccinated, at-risk laboratory personnel should receive appropriate booster doses of JE vaccine or be evaluated regularly for JEV-specific neutralizing antibodies to assure adequate titers.

### C. Japanese Encephalitis vaccination is NOT recommended for most short-term travelers.<sup>2,3</sup>

## 6. Contraindications:

Severe allergic reaction (e.g., anaphylaxis) after a previous dose.

## 7. Warnings and precautions:

1. Hypersensitivity to protamine sulfate.<sup>1</sup>
2. **Other vaccines:** Studies of concomitant administration of JE vaccine with hepatitis A vaccine and JE vaccine with rabies vaccine have showed non-inferiority compared to administering each vaccine alone. An additional study of concomitant administration of JE vaccine, rabies vaccine and meningococcal conjugate vaccine showed protective responses to all administered vaccines.<sup>2</sup>
3. **Pregnancy:** No studies of JE-VC in pregnant women have been conducted. Pregnancy is a precaution for use of JE-VC and in most instances, its administration to pregnant women should be deferred. However, pregnant women who must travel to an area where risk for JE virus infection is high should be vaccinated when the theoretical risk of immunization is outweighed by the risk of infection.<sup>3</sup>
4. **Newborns:** JE vaccine has not been tested in individuals  $\leq 2$  months of age.<sup>2</sup>
5. **Older adults:** In a post-licensure study, seroprotection and gross mean titers were substantially lower among adults  $\geq 65$  years of age compared to younger persons. No data exists on the safety or immunogenicity of an additional dose or early booster dose of JE vaccine for adults  $\geq 65$  years of age.<sup>2</sup>

## 8. Other considerations

- A. Although  $\leq 1\%$  of JEV infections results in clinical disease, JE is a devastating illness that has a case-fatality rate of 20%–30% and neurologic or psychiatric sequelae in 30%–50% of survivors. No specific treatment exists.<sup>2</sup>
- B. In all instances, travelers are advised to take personal precautions to reduce exposure to mosquito bites.<sup>3</sup>
- C. The decision to use JE-VC should balance the risks for exposure to the virus and for developing illness, the availability and acceptability of repellents and other alternative measures, and the side effects of vaccination.<sup>3</sup>
- D. Risk assessments should be interpreted cautiously because risk can vary within areas and from year to year.<sup>3</sup>
- E. Risk of JE for travelers to highly endemic areas during the transmission season can reach 5 to 50 cases per 100,000; the risk for most short-term travelers may be 1 per million or less.<sup>3</sup>
- F. **Adverse Events:** epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment must be available for immediate use in case of anaphylactic or acute hypersensitivity reaction.<sup>4</sup>
- G. **Immunocompromised:** individuals with altered immunocompetence may have reduced immune responses. Immunosuppressive therapies may decrease the immune response to IXIARO®<sup>1</sup>
- H. **Lactation:** Breastfeeding is not a contraindication or precaution to JE vaccine.<sup>2</sup>

## 9. Side effects and adverse reactions<sup>1</sup>

Japanese Encephalitis Vaccine	
<b>Infants and children</b>	
Pain, itching, redness or swelling at the injection site	Uncommon, up to 20%
Fever	Uncommon, up to 10%
Allergic reactions	Rare
<b>Adults</b>	
Soreness, redness or itching at the injection site, headache, fatigue	Somewhat common, up to 30%
Vomiting, fever, chills, rash	Rare, up to 5%
Allergic reactions	Rare

## 10. Storage and handling <sup>1</sup>

All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues	Notes
IXIARO <sup>®</sup> 1	Store at 2°–8°C (36°F–46°F)	Do not use if vaccine has been frozen. Report to health educator.  Store in original container. Protect from light.	No natural rubber latex.  Do not use after expiration date shown on the label.

## 11. Adverse events reporting

Report suspected adverse events to the Vaccine Adverse Events Reporting System (VAERS) online at <https://vaers.hhs.gov/reportevent.html>. VAERS Reporting Table: <https://vaers.hhs.gov/resources/infoproviders.html>

Event and interval from vaccination
A. Anaphylaxis or anaphylactic shock within 7 days; B. Shoulder injury related to vaccine administration within 7 days; C. Vasovagal syncope within 7 days; D. Guillain-Barré Syndrome within 42 days; E. Any acute complication or sequelae (including death) of above events; F. Any event described in the manufacturer's package insert as a contraindication to additional doses of vaccine.

To request this material in an alternative format (e.g., Braille) or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 971.673.0300 and 711 for TTY. For other questions, consult with the vaccine recipient's primary health care provider or a consulting physician.

Electronic copy of this immunization protocol is available at: [immunization protocols](#)

## 12. References

1. IXIARO<sup>®</sup> (2018) package insert, available at: [www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142569.pdf](http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142569.pdf). Accessed 21 April 2020.
2. CDC. Japanese Encephalitis Vaccine: Recommendations of the Advisory Committee on Immunization Practices. MMWR 2019; 68:#RR-2; 1-33. Available at: <https://www.cdc.gov/mmwr/volumes/68/rr/pdfs/rr6802a1-H.pdf>. Accessed 21 April 2020.
3. CDC. Japanese encephalitis. In: Health Information for International Travel 2018. Atlanta: U.S. Department of Health and Human Services, Public Health Service, 2018. Available at: [wwwnc.cdc.gov/travel/yellowbook/2018/infectious-diseases-related-to-travel/japanese-encephalitis](http://wwwnc.cdc.gov/travel/yellowbook/2018/infectious-diseases-related-to-travel/japanese-encephalitis). Accessed 21 April 2020.
4. Kroger AT, Duchin J, Vázquez M. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). [www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html](http://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html). Accessed 21 April 2020.

Japanese encephalitis among three U.S. travelers returning from Asia, 2003–2008. MMWR 2009; 58:737–40. Available at: [www.cdc.gov/mmwr/preview/mmwrhtml/mm5827a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5827a1.htm). Accessed 21 April 2020.