

IMMUNIZATION PROTOCOL FOR PHARMACISTS

LIVE YELLOW FEVER VACCINE

I. ORDER FOR ADMINISTRATION

1. You must be in possession of a Yellow Fever Stamp in order to administer this vaccine.
2. Screen for contraindications.
3. Provide a current Vaccine Information Statement (VIS), answering questions.
4. Obtain a signed Vaccine Administration Record (VAR).
5. Do not remove vaccine from refrigerator until ready to reconstitute it with the diluent supplied.
6. Add diluent slowly, let sit one to two minutes, then carefully swirl mixture to obtain a uniform suspension (avoid vigorous shaking, as this causes foaming). Suspension is slightly opalescent and light orange.
7. Vaccine must be kept cool and used within 60 minutes following reconstitution.
8. Give Yellow Fever vaccine (0.5 ml) subcutaneously as a single dose to individuals ≥ 18 years of age.
 - a. May be given simultaneously with all other vaccines, including travel vaccines.

Pharmacist signature

Date

Electronic copy of this protocol available at
<http://www.oregon.gov/dhs/ph/imm/provider/pharmpro.shtml>

Original provided courtesy of the Oregon State Public Health Division DHS Immunization Program

April 2008

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II. LICENSED LIVE YELLOW FEVER VACCINE

Product Name	Vaccine components	Acceptable Age Range	Preservatives
YF-VAX® (sanofi-pasteur)	17D-204 strain of YF virus grown in chicken embryos with gelatin and sorbitol as a stabilizer	≥9 months of age	None

III. STORAGE & HANDLING

- Yellow Fever vaccine is shipped within the US at a refrigerated temperature between 2° to 8°C (36° to 46°F).
- Upon receipt, store the vaccine powder and the accompanying dilute in the refrigerator between 2° and 8°C (as above).
- Use reconstituted vaccine within 1 hour. **Since the potency of the vaccine only persists for 1 hour, both single vials and multi-dose vials must be discarded if not used within ONE hour of reconstitution.**
- Reconstituted multi-dose vials can be refrigerated between clients until they are discarded after 1 hour.

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IV. INDICATIONS FOR USE

A. Persons living or traveling in endemic areas.

1. Persons ≥ 9 months of age traveling to or living in areas of South America or Africa where yellow fever infection is officially reported should be vaccinated.
2. Vaccination is also recommended for travel outside the urban areas of countries that do not officially report the disease but that lie in the yellow fever endemic zone (see CDC's *Health Information for International Travel 2008*).
<http://wwwn.cdc.gov/travel/yellowBookCh4-YellowFever.aspx>
3. The safety of yellow fever vaccination during pregnancy has not been established. The vaccine should be administered only if travel to an endemic area is unavoidable and if an increased risk for exposure exists. This ACIP MMWR available for reference:
<http://www.cdc.gov/MMWR/preview/mmwrhtml/rr5117a1.htm> p 8.
4. Laboratory personnel who might be exposed to virulent yellow fever virus by direct or indirect contact or by aerosols should be vaccinated.

B. Vaccination for international travel. For purposes of international travel, yellow fever vaccines produced by different manufacturers worldwide must be approved by the World Health Organization (WHO) and administered at an approved Yellow Fever Vaccination Center. Vaccinees should receive an International Certificate of Vaccination that has been completed, signed, and validated with the center's stamp where the vaccine is given.

Vaccination for international travel may be required under circumstances other than those specified herein. Some countries in Africa require evidence of vaccination from all entering travelers. Some countries may waive the requirements for travelers coming from non-infected areas and staying <2 weeks. Because requirements may change, current information should be obtained from the CDC's Travelers' Health website (wwwn.cdc.gov/travel).

Some countries require persons who have been in countries known or thought to harbor yellow fever virus, even if only in transit, to have a valid International Certificate of Vaccination. Such requirements

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may be strictly enforced, particularly for persons traveling from Africa or South America to Asia.

V. VACCINE SCHEDULE FOR YF- VAX®

Dose and Route: 0.5 ml SC		
DOSE	RECOMMENDED AGE	SPACING BETWEEN PRIMARY VACCINE & A BOOSTER
1	≥18 years of age ¹	10 years ²
<p>¹While this vaccine is licensed for persons ≥9 months of age, Oregon pharmacist's, by law, currently can't administer this vaccine to persons <18 years of age.</p> <p>²The International Health Regulations require revaccination at intervals of 10 years, although evidence from several studies suggests that yellow fever vaccine immunity persists for at least 30-35 years, and probably for life.</p>		

VI. CONTRAINDICATIONS & PRECAUTIONS

Contraindications	Precautions
<ol style="list-style-type: none"> 1. Persons who have ever had a life-threatening allergic reaction to eggs, chicken, gelatin or a previous yellow fever vaccine 2. No infant <6 months should be vaccinated because of the risk of serious post-vaccine encephalitis. 3. Infection with yellow fever vaccine virus poses a theoretical risk of encephalitis to patients with immunosuppression in association with acquired immunodeficiency syndrome (AIDS) or other manifestations of human immunodeficiency virus (HIV) infection, leukemia, lymphoma, generalized malignancy, or to those whose immunologic 	<ol style="list-style-type: none"> 1. Infants <9 months of age should not be immunized with YF-Vax®. If an infant 6–8 months cannot avoid travel to a yellow fever area, discuss vaccination with private provider before immunizing.² 2. Pregnant women and nursing mothers should avoid travel to yellow fever areas. If travel cannot be avoided, discuss vaccination with private provider before immunizing.^{3,4} 3. Because persons >65 years of age may be at increased risk for systemic reactions after vaccination, they should discuss risks and benefits with their medical provider before being immunized.

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responses are suppressed by corticosteroids, alkylating drugs, antimetabolites, or radiation. Such patients should not be vaccinated. ¹	
<p>¹If travel to a yellow fever-infected zone is necessary, patients should be advised of the risk, instructed in methods for avoiding vector mosquitoes, and supplied with vaccination waiver letters by their physicians.</p> <p>²Physicians considering vaccinating infants <9 months should contact the CDC for advice at 970-221-6400.</p> <p>³If international travel requirements constitute the only reason to vaccinate a pregnant woman, rather than an increased risk of infection, efforts should be made to obtain a waiver letter from the traveler's physician. Pregnant women who must travel to areas where the risk of yellow fever is high should be vaccinated.</p> <p>⁴ It is unknown whether the vaccine is excreted in human milk. No adverse events or transmission of the 17D vaccine viruses from a nursing mother to an infant has been reported. As a precautionary measure, vaccination of nursing mothers should be avoided.</p>	

VII. ADVERSE REACTIONS

1. Approximately 2% – 5% of patients develop mild symptoms such as headache, myalgia, low-grade fever, or malaise for 5–10 days after vaccination. Treatment should be symptomatic.
2. Immediate hypersensitivity reactions (rash, hive, or asthma) are uncommon (less than 1 per million) and occur principally among person with histories of egg allergy.
3. Gelatin is used as a stabilizer in yellow fever vaccine. It has been implicated as a cause of allergic reactions in other vaccines and may do the same in yellow fever vaccine.
4. Historically, yellow fever vaccine associated neurotropic disease was seen primarily among infants but more recently adult cases have been reported in first-time vaccine recipients. The frequency may range from four to six cases per million doses distributed. Another serious adverse reaction syndrome previously reported as “multiple organ system failure” is now called “yellow fever vaccine associated viscerotropic disease.” This reaction probably occurs along a spectrum of severity, from moderate illness with focal organ

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dysfunction to multiple system failure and death. All known cases have occurred in persons receiving their first dose of the vaccine. Crude estimates of reported frequency in the U.S. range from three to five cases per million doses distributed. The frequency may be higher for persons ≥ 76 years of age. Because of these rare adverse reactions, it is essential that the vaccine be administered only to persons truly at risk for exposure to yellow fever.

VIII. ADVERSE EVENT REPORTING

Adverse events following immunization must be reported to the Vaccine Adverse Events Reporting System (VAERS) at 1-800-822-7967. Forms and procedures can be found at the VAERS website: www.vaers.org. In addition, a copy of the completed VAERS form should be sent to the patient's primary provider, per ORS 855-041-0510

IX. OTHER CONSIDERATIONS

1. Live virus vaccines must be given concurrently; otherwise, 4 weeks should be allowed to elapse between sequential vaccinations.
2. Cholera and yellow fever vaccines should ideally be separated by a 3 week interval. If there are time constraints, however, they can be given simultaneously or at any time within the 3 week interval. Lower than normal antibody responses may occur from both vaccines.
Note: Cholera vaccine is no longer being produced in the United States.
3. A recent analysis of adverse events passively reported to the Vaccine Adverse Event Report System (VAERS) during 1990–1998 suggests that persons ≥ 65 years of age might be at increased risk for a variety of systemic adverse events following vaccination compared with persons 25–44 years of age.
4. There are no data on possible interference between yellow fever and typhoid, plague, rabies, or Japanese encephalitis vaccines.
5. Counsel the traveler on precautions against exposure to mosquitoes during travel.
6. International Certificates of Vaccination are valid for a period of 10 years commencing 10 days after primary vaccination or on the day of revaccination if within ten years of first injection.
7. Low-dose (10 mg prednisone or equivalent) or SHORT-TERM (<2 weeks) corticosteroid therapy or intra-articular, bursal, or tendon injections with corticosteroids should not be immunosuppressive and

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constitute no increased hazard to recipients of yellow fever vaccine. Persons who have had previously diagnosed asymptomatic HIV infections and who cannot avoid potential exposure to yellow fever virus should be offered the choice of vaccination. Vaccinees should be monitored for possible adverse effects. Since the vaccination of such persons may be less effective than that for non-HIV-infected persons, it may be desirable to test their neutralizing antibody response to vaccination before travel. For such determinations, contact the vaccinee's primary provider.

X. REFERENCES

CDC. Health Information for International Travel 2008, Atlanta: U.S. Department of Health and Human Services, Public Health Service, 2007; 362–434. Available at www.cdc.gov/travel/contentYellowBook.aspx

Sanofi pasteur. YF-Vax® package insert. Available at http://www.vaccineshoppe.com/US_PDF/YF-VAX_5055_5056_8.05.pdf

CDC. Yellow Fever Vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP). 2002. MMWR 2002; 51/(RR-17)_Available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5117a1.htm>

CDC. Yellow Fever Vaccine; recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1990; 39(RR-6). Available at www.cdc.gov/mmwr/preview/mmwrhtml/00001620.htm.

Tsai TF, Paul R, Lynberg MC, Letson GW. Congenital yellow fever virus infection after immunization in pregnancy. J Infect Dis 1993;168:1520–3.

Grabenstein JD. *ImmunoFacts: Vaccines and Immunologic Drugs 2008*. St. Louis Mo: Wolters Kluwer Health; 2007 p. 371–6.

For more information or to clarify any part of the above order, consult with the vaccine recipients' primary health-care provider, or contact the Oregon State Public Health Division's Immunization Program at (971) 673-0300