

YELLOW FEVER VACCINE

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Introduction

Yellow fever vaccine is a preparation of live, attenuated yellow fever virus.¹⁰⁶ Yellow fever vaccine is prepared using the 17D-204 strain of yellow fever virus.¹⁰⁶

Uses

■ Prevention of Disease Caused by Yellow Fever Virus

Yellow fever vaccine is used for active immunization for the prevention of yellow fever.¹⁰⁶ Yellow fever vaccine is commercially available in the US as a live, attenuated vaccine (YF-VAX[®]) prepared by culturing the 17D-204 strain of yellow fever virus.¹⁰⁶ Other yellow fever vaccines prepared by using either the 17D-204 or 17DD strain may be available in other countries.¹⁰⁰

YF-VAX[®] is used for the prevention of yellow fever in adults, adolescents, and children ≥9 months of age residing or traveling to yellow fever endemic areas.¹⁰⁶ It is difficult to predict the actual risk for a given individual living in or traveling to a known endemic or epidemic area due to variability of itineraries, behaviors, and seasonal incidence of disease.¹⁰⁶ A greater risk of contracting yellow fever is associated with living in or traveling to areas of Africa or South America where yellow fever is endemic or officially reported at the time of travel and with traveling outside the urban areas of countries that do not officially report the disease but lie in a yellow fever endemic zone.¹⁰⁶ YF-VAX[®] is also used for the prevention of yellow fever in adults, adolescents, and children ≥9 months of age traveling internationally through countries with yellow fever.¹⁰⁶ A valid International Certificate of Vaccination or Prophylaxis (ICVP) is required by some countries for individuals who have been in countries either known or thought to harbor yellow fever virus; the certificate becomes valid 10 days after vaccination with YF-VAX[®].¹⁰⁶ In addition, YF-VAX[®] is used for the prevention of yellow fever in laboratory personnel who might be exposed by direct or indirect contact or by aerosols to virulent yellow fever virus or to concentrated preparations of the yellow fever vaccine strain.¹⁰⁶

Yellow fever virus is a Flavivirus^{100,105,106,115}, closely related to Dengue, Japanese encephalitis virus, St. Louis encephalitis viruses, and West Nile virus (WNV).^{100,105} It has been estimated that there are 200,000 cases of yellow fever and 30,000 fatalities related to the disease reported annually worldwide.¹⁰⁰ Yellow fever virus is an arbovirus that is transmitted to humans through the bite of infected mosquitoes (principally *Aedes* or *Haemagogus* species).^{100,115} There are 3 yellow fever virus transmission cycles: sylvatic (jungle), intermediate (savanna), and urban.¹¹⁵ The sylvatic cycle involves transmission between non-human primates and mosquito species found in forest canopies; the intermediate cycle involves transmission from monkeys to humans or from humans to humans via those mosquitoes.¹¹⁵ The urban cycle of transmission occurs between humans and peridomestic mosquitoes.¹¹⁵

Disease caused by yellow fever virus ranges from a mild, nonspecific febrile illness to severe disease with jaundice, hemorrhagic symptoms, and eventually shock and multisystem organ failure.^{100,104,115} the case fatality rate for severe disease caused by yellow fever virus is 30–60%.¹¹⁵ Because there are no specific treatments available, prevention through vaccination with yellow fever vaccine is necessary to reduce morbidity and mortality associated with yellow fever virus infection.^{100,104,115} During 2016–2018, more than 37 travel-associated cases of yellow fever were reported in unvaccinated travelers who were residents of non-endemic areas or countries, including an American traveler to Peru.¹¹⁵ Travel-associated cases have become uncommon, likely due to decreases in the occurrence of large yellow fever outbreaks and decreases in travel during the COVID-19 pandemic.¹¹⁵

Yellow fever virus is endemic and intermittently epidemic in sub-Saharan Africa and tropical South America.^{100,115} Most disease due to yellow fever virus is due to sylvatic or intermediate transmission cycles.¹¹⁵ The risk of a traveler acquiring yellow fever depends on several factors, including vaccination status, use of personal protective measures against mosquito bites, travel locations, season, duration of exposure, occupational and recreational activities while traveling, and the local rate of yellow fever virus transmission at the time of travel.^{100,104,115}

The Centers for Disease Control and Prevention (CDC) maintains a list of countries with risk for yellow fever virus transmission.¹¹⁵ In Africa, transmission of the yellow fever virus is seasonal.¹¹⁵ Yellow fever virus transmission in West Africa increases during the middle of the rainy season, around August, and peaks during the early dry season in October.¹¹⁵ Yellow fever virus transmission in East Africa is generally less predictable due to long periods (years) often passing between virus activity in this region; when transmission occurs, its seasonality is similar to that of West Africa.¹¹⁵ In South America, the risk of infection from yellow fever virus via sylvatic vectors is highest during the rainy season from January to May, with peaks during February and March.¹¹⁵

Clinical Experience

There have been no human efficacy studies performed with yellow fever vaccine.¹⁰⁰ Titers of yellow fever virus neutralizing antibodies in sera of vaccine recipients are efficacy surrogates.¹⁰⁶ In an animal study, a log₁₀ neutralization index (LNI) ≥0.7 was shown to protect 90% of monkeys from lethal intracerebral challenge; an LNI ≥0.7 is the definition of seroconversion in yellow fever vaccine clinical trials.¹⁰⁶ In 24 uncontrolled studies worldwide, neutralizing antibody responses to 17D vaccines in 2529 adults and 991 infants and children were evaluated; the seroconversion rate was >91% in all but 2 studies and never less than 81%.¹⁰⁶ Five of the 24 uncontrolled studies were conducted in the US and included 208 adults who received YF-VAX®.¹⁰⁶ The seroconversion rate was 81% in a single US study and 97–100% in the other 4 US studies.¹⁰⁶

A randomized, double-blind, controlled, phase 3 study conducted at 9 centers in the US assessed the immunogenicity of YF-VAX® and another 17D-204 vaccine.^{106,157} Of the 312 adults who received YF-VAX® and were evaluated serologically, 99.3% seroconverted.^{106,157} The mean LNI at 31 days after administration of YF-VAX® was 2.21.^{106,157}

In 2 separate clinical trials of 17D-204 yellow fever vaccines, seroconversion occurred in 90 and 100% of individuals within 10 and 14 days after vaccination, respectively.¹⁰⁶

Clinical Perspective

The CDC's Advisory Committee on Immunization Practices (ACIP) and other organizations (e.g., American Academy of Pediatrics [AAP]) provide recommendations for the prevention of yellow fever.^{100,105,115,155,156} Yellow fever vaccination is recommended in adults, adolescents, and children ≥9 months of age traveling to or living in areas at risk for yellow fever virus transmission in Africa and South America.^{100,105,115}

Additionally, some countries require proof of yellow fever vaccination for entry.^{100,105,115} The CDC maintains a list of yellow fever vaccine recommendations by country.¹³⁵ Since yellow fever vaccine has been associated with serious adverse effects, clinicians should only vaccinate people at risk of exposure.¹¹⁵ Decisions regarding the use of yellow fever vaccine should also involve careful consideration of contraindications and precautions prior to administration.^{100,115}

Primary immunization with a single dose of yellow fever vaccine provides long-lasting protection and is adequate for most travelers; however, revaccination is recommended for certain travelers who will be visiting countries with a risk of yellow fever virus transmission (e.g., women who received primary immunization during pregnancy, individuals who received a hematopoietic stem cell transplant [HSCT] after receiving primary immunization, individuals who had human immunodeficiency virus [HIV] infection when they received their last dose of yellow fever vaccine).^{104,105} Revaccination (booster dose) may be given to travelers who received their last dose of yellow fever vaccine at least 10 years previously and who will be in higher-risk settings based on location, season, activities, and duration of travel.^{104,105,115}

HIV-specific guidelines from the National Institutes of Health (NIH), the HIV Medicine Association, and the Infectious Diseases Society of America (IDSA) recommend yellow fever vaccination in adults and adolescents at risk for yellow fever virus acquisition (e.g., by traveling to or living in areas at risk based on season, location, activities, and duration).¹⁵⁵ When indicated, vaccination should be provided at least 10 days prior to the expected exposure.¹⁵⁵ For travelers <59 years of age and asymptomatic with CD4 count >500 cells/mm³, a single dose of yellow fever vaccine is recommended; revaccination is recommended in >10 years if risk remains.¹⁵⁵ Yellow fever vaccination can also be given to children 9 months to <6 years of age with CD4 percentages >24% of total lymphocytes or to children ≥6 years of age with a CD4 count ≥500 cells/mm³.¹⁵⁶ In adults, adolescents, and children ≥6 years of age with CD4 counts of 200–499 cells/mm³ or children 6 months to 6 years of age with CD4 percentages of 15–24% of total lymphocytes, yellow fever vaccination may be considered depending on risk.^{155,156} Yellow fever vaccine is contraindicated for all children <6 months of age, for all adults, adolescents, and children with symptomatic HIV or CD4 count <200 cells/mm³ (or CD4 count <15% total lymphocytes for children <6 years of age).^{155,156} If the only reason to vaccinate an individual with HIV is due to international travel requirements, versus an increased risk for acquiring yellow fever infection, the individual should be excused from vaccination and be issued a medical waiver to fulfill health regulations.^{155,156}

In addition to vaccination, travelers should take precautions to avoid exposure to mosquitoes since this reduces the risk for yellow fever and other mosquito-borne infectious diseases.^{100,115} Travelers to yellow fever virus areas should be advised of the importance of taking measures to reduce contact with mosquitoes (e.g., staying in air-conditioned or well-screened quarters, wearing long-sleeved shirts and long pants to cover most of the body, using appropriate insect repellents, using mosquito nets between dusk and dawn).^{100,115}

To prevent importation and indigenous transmission of yellow fever virus, international health regulations (IHR) of the World Health Organization (WHO) allow countries to require proof of yellow fever vaccination documented on a validated ICVP as a condition of entry.^{100,115} Some countries require evidence of vaccination against yellow fever from all entering travelers, while others only require vaccination for travelers coming from, or traveling through, countries with risk of yellow fever virus transmission.^{100,115} Travelers with contraindications to yellow fever vaccine and who cannot avoid travel to a country requiring vaccination should obtain a medical waiver before embarking on travel.^{100,115} Requirements regarding ICVPs may be strictly enforced and travelers arriving without a valid ICVP or medical waiver may be quarantined for up to 6 days, denied entry, or possibly vaccinated or revaccinated at the point of entry.^{100,115}

For the purposes of international travel, yellow fever vaccination must be completed at an approved yellow fever vaccination center.^{100,115} In the US, local or state public health departments are responsible for designating nonfederal yellow fever vaccination centers.^{100,115} Vaccine recipients should receive a completed ICVP that is signed and validated with the official uniform stamp of the yellow fever vaccination center where the vaccine was given.^{100,106,115} These certificates are valid beginning 10 days after vaccination with yellow fever vaccine.^{100,106,115}

Information on country-specific requirements for yellow fever vaccination for travelers and on regulations regarding ICVPs and medical waivers are available from CDC.^{115,135}

ACIP recommends administration of yellow fever vaccine for laboratory personnel who might be exposed to virulent yellow fever virus or to concentrated preparations of the yellow fever vaccine virus strain by direct or indirect contact or by aerosols.¹⁰⁰ Laboratory workers who routinely handle wild-type yellow fever virus should be tested for yellow fever virus-

specific neutralizing antibody titers at least every 10 years after primary immunization to determine whether revaccination (booster dose) is indicated.¹⁰⁴ Laboratory workers who are unable to have neutralizing antibody titers measured should receive a dose of yellow fever vaccine every 10 years if they remain at risk.¹⁰⁴,

Dosage and Administration

■ General

Pretreatment Screening

- Screen for history of acute hypersensitivity or anaphylaxis to eggs or egg products.¹⁰⁶,
- In women who are postpartum, determine whether the mother is breast-feeding.¹⁰⁶,
- Screen for severe immunosuppression including patients with AIDS, leukemia, lymphoma, thymic disease, or generalized malignancy; patients taking systemic corticosteroids, alkylating drugs, antimetabolites, or other immunomodulatory drugs; and patients undergoing radiation therapy.¹⁰⁶,

Patient Monitoring

- Observe patients for at least 15 minutes after vaccine administration for signs and symptoms of allergic reaction to the vaccine.¹⁰⁰, Syncope (vasovagal or vasodepressor reaction; fainting) may occur following vaccination; such reactions occur most frequently in adolescents and young adults.¹³⁴, If syncope occurs, observe the patient until symptoms resolve.¹³⁴,
- If administered to patients ≥60 years of age, monitor closely for severe systemic adverse reactions.¹⁰⁶,

Dispensing and Administration Precautions

- Ensure appropriate medical treatment and supervision is available to manage possible anaphylactic reactions following administration of the vaccine.¹⁰⁶,
- Ensure procedures are in place to prevent falling and injury and to manage syncope before and after vaccination.¹⁰⁶,

■ Administration

Yellow fever vaccine is administered by subcutaneous injection.¹⁰⁶, The vaccine should be reconstituted prior to administration.¹⁰⁶,

Yellow fever vaccine should not be administered by IM, intravascular, or intradermal routes.^{100,106}, However, if the vaccine is inadvertently given IM, the US Public Health Service Advisory Committee on Immunization Practices (ACIP) states that the immunologic response to the vaccine probably will be unaffected and a repeat dose given by subcutaneous injection is unnecessary.¹⁰⁰,

In the US, yellow fever vaccine can only be administered at certain sites authorized to issue a valid International Certificate of Vaccination or Prophylaxis (ICVP).^{100,106,115},

Store vaccine vials at 2–8°C and do not freeze.¹⁰⁶, The half-life of the vaccine is reduced from approximately 14 days when stored at 35–37°C to 3–4.5 days at 45–47°C.¹⁰⁶, Improper storage or handling of vaccines may reduce vaccine potency resulting in reduced or inadequate immune responses in vaccine recipients.¹³⁴, All vaccines should be inspected upon delivery and monitored during storage to ensure that the appropriate temperature is maintained.¹³⁴,

Vaccine that has been mishandled or has not been stored at the recommended temperature should not be administered.¹³⁴, If there are concerns about mishandling, the manufacturer or state or local immunization or health departments should be contacted for guidance on whether the vaccine is usable.¹³⁴,

Subcutaneous injections should be administered at a 45° angle using a 5/8 to 3/4 inch, 23- to 25-gauge needle.¹³⁴, Subcutaneous injections usually should be made into the upper-outer triceps area in adults, adolescents, and children ≥12 months of age or into the anterolateral thigh in infants <12 months of age.¹³⁴,

The vial and any unused portion of reconstituted vaccine must be disposed of properly (e.g., sterilized, disposed of as medical waste).¹⁰⁶,

When multiple parenteral vaccines are administered during a single health-care visit, each vaccine should be given with a different syringe and at different injection sites.¹³⁴, Injection sites should be separated by at least 1 inch (if anatomically feasible) to allow appropriate attribution of any local adverse effects that may occur.¹³⁴,

Reconstitution

Yellow fever vaccine is reconstituted by using only the 0.9% sodium chloride diluent supplied by the manufacturer.¹⁰⁶, The appropriate volume of diluent specified on the vaccine label should be withdrawn with a sterile needle into a syringe using aseptic technique and slowly added to the vaccine vial.¹⁰⁶, The vial should be allowed to stand for 1–2 minutes and then carefully swirled until a uniform suspension is obtained.¹⁰⁶, Vigorous shaking should be avoided since this tends to cause foaming of the suspension.¹⁰⁶, Because yellow fever vaccine and the diluent supplied by the manufacturer do not contain preservatives, the vaccine should be used within 1 hour following reconstitution.¹⁰⁶,

Reconstituted yellow fever vaccine should appear as a slightly pink-brown suspension and should not be used if it is discolored or contains extraneous particulate matter.¹⁰⁶,

■ Dosage

Adults

Prevention of Disease Caused by Yellow Fever Virus

For primary immunization in adults, administer yellow fever vaccine as a single 0.5-mL dose at least 10 days prior to potential exposure to yellow fever virus.^{100,106,115,}

An additional dose of the vaccine may be given to individuals who might not have had an adequate or sustained immune response to prior vaccination and who continue to be at risk for exposure to yellow fever virus.^{106,} Such individuals include women who were vaccinated during pregnancy, hematopoietic stem cell transplant (HSCT) recipients, and HIV-infected persons.^{106,}

A booster dose may be given to individuals who were last vaccinated against yellow fever at least 10 years prior and who are at increased risk for yellow fever disease either because of location and duration of travel or because of more consistent exposure to virulent virus.^{106,} Such individuals include travelers who plan to spend a prolonged period in endemic areas or who plan to travel to highly endemic areas such as rural West Africa, and laboratory personnel who handle virulent yellow fever virus or concentrated preparations of the yellow fever vaccine virus strains.^{106,}

Pediatric Patients

Prevention of Disease Caused by Yellow Fever Virus

For primary immunization in adolescents and children ≥9 months of age, administer yellow fever vaccine as a single 0.5-mL dose at least 10 days prior to potential exposure to yellow fever virus.^{100,106,115,}

An additional dose of the vaccine may be given to individuals who might not have had an adequate or sustained immune response to prior vaccination and who continue to be at risk for exposure to yellow fever virus.^{106,} Such individuals include women who were vaccinated during pregnancy, HSCT recipients, and HIV-infected persons.^{106,}

A booster dose may be given to individuals who were last vaccinated against yellow fever at least 10 years prior and who are at increased risk for yellow fever disease either because of location and duration of travel or because of more consistent exposure to virulent virus.^{106,} Such individuals include pediatric travelers who spend a prolonged period in endemic areas or who plan to travel to highly endemic areas such as rural West Africa.^{106,}

Special Populations

Hepatic Impairment

The manufacturer makes no specific dosage recommendations for patients with hepatic impairment.^{106,}

Renal Impairment

The manufacturer makes no specific dosage recommendations for patients with renal impairment.^{106,}

Geriatric Patients

The manufacturer makes no specific dosage recommendations for geriatric patients.^{106,} The risk of severe systemic adverse reactions is higher in patients 60 years of age and older.^{106,} Use with caution and monitor closely.^{106,}

Cautions

■ Contraindications

- Hypersensitivity to any component including eggs or egg products.^{106,}
- Patients <9 months of age (per manufacturer); the Centers for Disease Control and Prevention (CDC) states that vaccination should be avoided in patients <9 months when possible but can be considered in patients 6–8 months of age if benefits outweigh risks.^{106,115,}
- Women who are lactating and providing breastmilk to infants <9 months of age.^{106,}

- Severe immunosuppression or underlying disease (e.g., leukemia, lymphoma, thymic disease, generalized malignancy), gammaglobulin deficiency (e.g., agammaglobulinemia, hypogammaglobulinemia, dysgammaglobulinemia), immunosuppression secondary to AIDS or other manifestations of HIV infection (including those with CD4 T lymphocyte counts <200/mL or <15% total lymphocytes for children <6 years of age), or those receiving immunosuppressive or immunomodulatory therapy (e.g., alkylating agents, antimetabolites, corticosteroids, interleukin-1 blocking agents, monoclonal antibodies targeting immune cells, tumor necrosis factor alpha [TNF- α] inhibitors, radiation).^{100,106,115,}

■ Warnings/Precautions

Severe Allergic Reactions

Severe allergic reactions (e.g., anaphylaxis) may occur, even in individuals with no prior history of hypersensitivity to the vaccine components.¹⁰⁶ Ensure appropriate medical treatment and supervision is available to manage possible anaphylactic reactions following administration of the vaccine.¹⁰⁶

The possibility of a hypersensitivity reaction to gelatin, which is present in yellow fever vaccine as a stabilizer, should be considered.¹⁰⁶ The US Public Health Service Advisory Committee on Immunization Practices (ACIP) states that patients with a history of anaphylaxis to gelatin or gelatin-containing products should be evaluated by an allergist before receiving gelatin-containing vaccines.^{134,}

Testing for Hypersensitivity Reactions

Because of the risk of a severe hypersensitivity reaction (e.g., anaphylaxis) if yellow fever vaccine is administered to an individual hypersensitive to eggs or chicken protein, a scratch and an intradermal skin test is recommended prior to administration of the vaccine in anyone suspected of being sensitive to eggs.¹⁰⁶ Epinephrine should be available during such testing in case an immediate sensitivity reaction occurs.¹⁰⁶

For the scratch test, a 1:10 dilution of yellow fever vaccine in 0.9% sodium chloride should be used.¹⁰⁶ A drop of the 1:10 dilution should be put on a superficial scratch, prick, or puncture on the volar surface of the forearm and positive (histamine) and negative (0.9% sodium chloride) controls should be used.¹⁰⁶ The scratch test is read after 15–20 minutes.¹⁰⁶ A positive reaction consists of a wheal that is 3 mm larger than that of the 0.9% sodium chloride control, usually with surrounding erythema.¹⁰⁶ The histamine control must be positive for valid interpretation.¹⁰⁶ If the scratch test is negative, an intradermal test should be performed.¹⁰⁶

For the intradermal skin test, 0.02 mL of a 1:100 dilution of yellow fever vaccine in 0.9% sodium chloride injection is given intradermally on the volar surface of the forearm.¹⁰⁶ Positive and negative control intradermal tests should be performed concurrently at separate sites.¹⁰⁶ A positive intradermal skin test reaction consists of a wheal that is 5 mm or larger in diameter than the negative control with surrounding erythema.¹⁰⁶

If vaccination with yellow fever vaccine is considered essential in an individual with a history of severe egg sensitivity and positive sensitivity test, desensitization can be considered.^{100,106,115} Perform desensitization only under the direct supervision of a physician experienced in the management of anaphylaxis with necessary emergency equipment immediately available.^{100,106} Administer the following successive doses subcutaneously at 15–20 minute intervals: 0.05 mL of a 1:10 dilution, 0.05 mL of undiluted vaccine, 0.1 mL of undiluted vaccine, 0.15 mL of undiluted vaccine, 0.2 mL of undiluted vaccine.¹⁰⁶

Yellow Fever Vaccine-Associated Viscerotropic Disease

Age greater than 60 years is a risk factor for yellow fever vaccine-associated viscerotropic disease (YEL-AVD), which may present as non-specific multi-organ system failure or can be similar to fulminant yellow fever caused by wild-type yellow fever virus, with liver failure and internal bleeding, leading to death.¹⁰⁶ YEL-AVD has been reported to occur only after the first dose of yellow fever vaccine; there have been no reports of YEL-AVD following a booster dose.¹⁰⁶ Weigh the risks and benefits of vaccination and the risk for exposure to yellow fever virus prior to vaccination in individuals 60 years of age and older.¹⁰⁶

There is evidence suggesting that thymic dysfunction is an independent risk factor for development of YEL-AVD, and clinicians should ask about a history of thymus disorder (e.g., myasthenia gravis, thymoma, prior thymectomy) prior to administration of yellow fever vaccine as the vaccine is contraindicated in such individuals.¹⁰⁶ However, ACIP and CDC state that the vaccine can be used in individuals who have undergone incidental surgical removal of their thymus or have had direct radiation therapy in the distant past since there is no evidence of immune dysfunction or increased risk of yellow fever vaccine-associated serious adverse effects in such individuals.^{100,115,}

Yellow Fever Vaccine-Associated Neurotropic Disease

Age greater than 60 years and immunosuppression are risk factors for post-vaccinal encephalitis, also known as yellow fever vaccine-associated neurotropic disease (YEL-AND).¹⁰⁶ Almost all cases of YEL-AND have been in first-time vaccine recipients.¹⁰⁶

Weigh the risks and benefits of vaccination and the risk for exposure to yellow fever virus prior to vaccination in individuals 60 years of age and older.¹⁰⁶

Protection from Yellow Fever Infection

Vaccination may not protect 100% of individuals from yellow fever infection.¹⁰⁶

Syncope

Syncope can occur following or even before vaccination.¹⁰⁶ Ensure procedures are in place to prevent falling and injury and to manage syncope.¹⁰⁶

Asymptomatic HIV Infection

The rate of seroconversion following yellow fever vaccination is reduced in individuals with asymptomatic HIV infection and appears to depend on HIV viral load and CD4+ T-cell count.¹⁰⁶ Ensure documentation of a protective antibody response before travel.¹⁰⁶

Acute Illness

The decision whether to administer or delay administration of yellow fever vaccine in an individual with a current or recent febrile illness depends largely on the severity and etiology of the illness.^{134,}

The manufacturer does not address administration of the vaccine to patients with acute or febrile disease.^{106,}

ACIP states that vaccination of individuals with moderate or severe acute illness (with or without fever) generally should be deferred until they have recovered to avoid superimposing adverse effects of the vaccine on the underlying illness or to avoid mistakenly concluding that a manifestation of the underlying illness resulted from vaccination.^{134,}

Chronic Illness

Yellow fever vaccine is contraindicated in individuals with chronic illness associated with severe immunosuppression.^{100,105,106,115,134,}

Data are limited regarding possible increased incidence of adverse effects or decreased vaccine efficacy if yellow fever vaccine is administered to patients with other chronic medical conditions (e.g., diabetes mellitus, renal disease, hepatitis C virus [HCV] infection or other liver disease).^{115,} Use of the vaccine in such patients should be considered with caution, taking into account the patient's general level of immune competence, disease severity and duration, and comorbidities.^{115,}

Transmission of Vaccine Virus

Yellow fever vaccine contains live, attenuated yellow fever virus.^{106,} Low-level viremia caused by the yellow fever vaccine virus (17D-204 strain) may occur 3–7 days after administration of the vaccine and persist for 1–3 days.^{100,} This level of viremia is high enough for the vaccine virus to be transmitted through blood products.^{100,}

Transfusion-related transmission of yellow fever vaccine virus has been documented in a few individuals who received blood products that were collected from individuals who received yellow fever vaccine 4 days before their blood donation.^{100,} ACIP states that vaccine recipients should be advised to defer blood donation for 2 weeks after receiving yellow fever vaccine.^{100,}

There is evidence that yellow fever vaccine virus can be transmitted via milk to nursing infants.^{100,106,122,123,}

Duration of Immunity

The duration of protection and need for revaccination or additional (booster) doses after primary immunization with yellow fever vaccine has not been fully determined.^{102,103,104,106,} Following primary immunization with a single dose of yellow fever vaccine in healthy individuals, 80–100% of vaccine recipients develop protective levels of yellow fever virus neutralizing antibodies within 10 days and there is some evidence that this immunity may persist for at least 30–35 years and possibly for life.^{100,101,103,106,}

Revaccination (booster dose) of yellow fever vaccine boosts levels of yellow fever virus-specific neutralizing antibody,^{100,106,} and there is some evidence that the degree of this increase is inversely correlated with the preexisting level of antibody.^{100,}

The manufacturer states that a booster dose may be given to individuals who were last vaccinated against yellow fever at least 10 years prior and who are at increased risk for yellow fever disease either because of location and duration of travel or because of more consistent exposure to virulent virus.^{106,} Such individuals include travelers who plan to spend a prolonged period in endemic areas or who plan to travel to highly endemic areas such as rural West Africa, and laboratory personnel who handle virulent yellow fever virus or concentrated preparations of the yellow fever vaccine virus strains.^{106,}

ACIP states that a single primary dose of yellow fever vaccine provides long-lasting protection and is adequate for most travelers.^{104,} However, because data are not available on vaccine efficacy or protective antibody titers (i.e., seroprotection) related to long-term immunogenicity after vaccination with yellow fever vaccine, ACIP recommends that certain individuals who may have had a less robust or less sustained immune response to the vaccine, certain travelers who will be in higher-risk settings, and laboratory personnel at continued high risk of exposure to yellow fever virus should receive revaccination (booster dose) of yellow fever vaccine.^{104,}

The World Health Organization (WHO) states that a single primary dose of yellow fever vaccine provides sustained immunity and lifelong protection against disease caused by yellow fever virus and that revaccination (booster dose) every 10 years is no longer considered necessary.^{115,} WHO states that an International Certificate of Vaccination or Prophylaxis (ICVP) is considered valid for the lifetime of the vaccine recipient.^{115,}

Specific Populations

Pregnancy

Animal reproduction studies have not been conducted with yellow fever vaccine.^{106,} It is also not known whether yellow fever vaccine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.^{106,} Yellow fever vaccine should be given to a pregnant woman only if clearly needed.^{106,}

Case reports and studies on use of another formulation of yellow fever vaccine have not demonstrated adverse effects; however, transplacental infection with 17D vaccine viruses can occur and efficacy in seroconversion with the vaccine may be reduced during pregnancy.^{106,}

Live, attenuated virus vaccines administered during pregnancy pose a theoretical risk to the fetus and such vaccines generally are contraindicated during pregnancy, unless the disease to be prevented poses a greater risk to the pregnant woman or fetus than the vaccine.^{105,134} The sequelae of yellow fever infection are not altered by pregnancy and efforts should be made to postpone travel to areas with a substantial risk of exposure to yellow fever until after delivery when the vaccine can be administered.^{105,115}

If travel to high-risk areas is unavoidable during pregnancy and the risks of the vaccine are thought to outweigh the risks of exposure to yellow fever virus, pregnant women should be advised of the risk, instructed in methods for avoiding bites by vector mosquitoes, and provided with a medical waiver letter to use with the required ICVP to fulfill international health regulations.^{100,105,115}

Because some data indicate that the seroconversion rate after vaccination with yellow fever vaccine may be lower in pregnant women compared with other healthy adults, consideration should be given to performing serologic testing to document seroconversion after vaccination.^{100,115} Appropriate state health departments or the CDC (970-221-6400) should be contacted for information on serologic testing.¹¹⁵

Although specific data are not available, ACIP and CDC state that women who receive yellow fever vaccine and are planning to become pregnant should wait at least 4 weeks after vaccination before conceiving.^{100,115}

Lactation

There is evidence that yellow fever vaccine virus can be transmitted via milk from nursing mothers to their infants.^{100,122,123} In one reported case, a nursing mother in Brazil received a dose of yellow fever vaccine (prepared using the 17DD strain of yellow fever virus) at 15 days postpartum and her infant, who was exclusively breast-fed, was hospitalized 8 days later with seizures and possible meningoencephalitis.¹²³ Yellow fever vaccine virus, identical to the 17DD vaccine strain, was detected in the infant's CSF and yellow fever-specific immunoglobulin M (IgM) antibodies were present in the infant's serum and CSF, indicating transmission and infection with yellow fever vaccine virus.¹²³

Because of the potential for serious adverse reactions in nursing infants, weigh the risks and benefits when deciding whether to discontinue nursing or to not administer the vaccine, taking into account the importance of the vaccine to the mother.¹⁰⁶

As of July 2015, 3 vaccine-associated neurotropic disease cases have been reported worldwide in exclusively breast-fed infants whose mothers were vaccinated with yellow fever vaccines, including one case reported after vaccination with YF-VAX[®].¹⁰⁶ All 3 infants were diagnosed with encephalitis and were less than 1 month of age at the time of exposure.¹⁰⁶ Because age <9 months is a risk factor for yellow fever vaccine-associated neurotropic disease, yellow fever vaccine is contraindicated in lactating women who are providing breastmilk to infants <9 months of age.¹⁰⁶ Discuss the risks and benefits of vaccination with lactating women who are providing breastmilk to infants ≥9 months of age.¹⁰⁶

Pediatric Use

Vaccination of infants <9 months of age is contraindicated because of the risk of YEL-AND.¹⁰⁶

The CDC Yellow Book and the American Academy of Pediatrics (AAP) state that vaccination of infants less than 6 months of age is contraindicated.^{100,105,115} Caution is advised with use in **infants 6–8 months of age [off-label]**[†] due to the risk of YEL-AND.^{100,105,115} Two cases of YEL-AND have been reported in infants 6–8 months of age.¹¹⁵ By 9 months of age, risk for YEL-AND is believed to be substantially lower.¹¹⁵ Whenever possible, travel to yellow fever-endemic countries for children 6–8 months of age should be postponed or avoided.^{100,105,115}

Geriatric Use

There is an increased risk of severe systemic adverse reactions to YF-VAX[®] in individuals 60 years of age and older.^{100,106,115}

ACIP and CDC state that yellow fever vaccine should be used with caution in adults 60 years of age or older, especially in those receiving their first dose of the vaccine.^{100,115}

If travel is unavoidable, a decision regarding whether to vaccinate a geriatric individual 60 years of age or older should be based on the risks and benefits of the vaccine in the context of the destination-specific risk for exposure to yellow fever virus.^{100,115}

Monitor geriatric patients for signs and symptoms of yellow fever vaccine-associated viscerotropic disease, which typically occurs within 10 days post-vaccination.¹⁰⁶

■ Common Adverse Effects

Adverse reactions include mild headaches, myalgia, low-grade fevers, or other minor symptoms for 5–10 days, local reactions including edema, hypersensitivity, pain or mass at the injection site, and hypersensitivity reactions characterized by rash, urticaria, and/or asthma (occurring primarily in patients with a history of allergy to eggs or other vaccine components).^{106,}

Drug Interactions

■ Blood Products

The US Public Health Service Advisory Committee on Immunization Practices (ACIP) states that yellow fever vaccine may be administered concurrently with (at a different site) or at any time before or after blood products (e.g., whole blood, packed red blood cells, plasma) because blood products available in the US are unlikely to contain a substantial amount of antibody to yellow fever vaccine virus.^{134,} However, because there is evidence that yellow fever vaccine virus can be transmitted via blood products collected from individuals who received yellow fever vaccine a few days before their blood donation, ACIP states that vaccine recipients should be advised to defer blood donation for 2 weeks after receiving yellow fever vaccine.^{100,}

■ Chloroquine

Although chloroquine inhibits replication of yellow fever vaccine in vitro, it does not appear to adversely affect antibody responses to yellow fever vaccine among persons receiving chloroquine.^{106,}

■ Corticosteroid Therapy

Oral prednisone or other systemic corticosteroid therapy, depending on dose and duration of exposure, may have an immunosuppressive effect on recipients of yellow fever vaccine that potentially decreases immunogenicity and increases the risk of adverse events.^{106,}

ACIP states that short-term (less than 2 weeks), low- to moderate-dose (less than 20 mg of prednisone daily or equivalent) systemic corticosteroid therapy; long-term, alternate-day treatment with short-acting systemic corticosteroid therapy; maintenance physiologic doses (replacement therapy); topical (e.g., cutaneous, ophthalmic) or inhaled corticosteroid therapy; or intra-articular, bursal, or tendon injections with corticosteroids should not be immunosuppressive and do not usually contraindicate vaccination with live virus vaccines.^{100,} Although the immunosuppressive effects of corticosteroids can vary, these experts state that a dose equivalent to either 2 mg/kg or greater or a total daily dosage of 20 mg or greater of prednisone or its equivalent in individuals weighing more than 10 kg when administered for 2 weeks or longer is considered sufficiently immunosuppressive to contraindicate use of live attenuated vaccines.^{100,134,} ACIP states that vaccination with live virus vaccines should be deferred for at least 1 month after high-dose systemically-absorbed corticosteroid therapy that has been administered for 14 days or longer is discontinued.^{134,}

ACIP states that individuals with leukemia in remission who have not received chemotherapy for at least 3 months may receive live viral vaccines.^{134,}

■ Immune Globulin

In a prospective study, persons given 5 mL of commercially available immune globulin did not experience alterations in immunologic responses to the yellow fever vaccine.^{106,}

The US Centers for Disease Control and Prevention (CDC), ACIP, and American Academy of Pediatrics (AAP) state that yellow fever vaccine may be administered concurrently with (at a different site) or any time before or after immune globulin or specific immune globulin (hyperimmune globulin) preparations (e.g., IGIM, IGIV, hepatitis B immune globulin [HBIG], rabies immune globulin [RIG], varicella zoster immune globulin [VZIG]).^{134,} Data indicate that immune globulin does not interfere with the immune response to yellow fever vaccine.^{100,106,111,115,}

■ Tuberculin Skin Test

Although the effect of yellow fever vaccine, if any, on tuberculin testing has not been determined,^{100,134,} another live virus vaccine (measles virus vaccine live; no longer commercially available in the US as a monovalent vaccine) has been reported to temporarily suppress tuberculin skin sensitivity.^{134,}

ACIP states that a tuberculin skin test can be given during the same health-care visit as yellow fever vaccine; if not given simultaneously, the tuberculin test should be delayed for at least 4 weeks after the vaccine dose.^{100,134,} However, vaccination with the yellow fever vaccine should not be delayed based only on a theoretical concern about a possible interaction with tuberculin skin testing.^{134,}

■ Vaccines

Inactivated vaccines can be administered before, after, or at the same time as yellow fever vaccine.^{115,}

ACIP recommends that other live viral vaccines can be given at the same time as yellow fever vaccine.^{115,} If not given simultaneously, wait 1 month to administer another live vaccine.^{115,}

Oral Ty21a typhoid vaccine (Vivotif®) can be administered simultaneously or at any interval before or after yellow fever vaccine.^{115,}

No data are available on the immune response to nasally administered live attenuated influenza vaccine given concurrently with yellow fever vaccine.^{115,}

The following vaccines have been administered with yellow fever vaccine at separate injection sites: measles (Schwartz strain) vaccine, diphtheria and tetanus toxoids and whole cell pertussis vaccine (DTP), hepatitis A and hepatitis B vaccines, meningococcal vaccine (Menomune® A/C/Y/W-135), and typhoid vaccine (Typhim Vi®).^{106,109,121,134,}

The potential for interference between yellow fever vaccine and rabies or Japanese encephalitis vaccines has not been established.^{106,}

Description

Yellow fever vaccine is used to stimulate active immunity through the humoral immune response to yellow fever virus infection by inducing production of yellow fever virus-specific neutralizing antibodies.^{106,} Yellow fever is an acute viral illness caused by the yellow fever virus, a Flavivirus.^{100,105,106,115,}

Infection with yellow fever virus can result in a subclinical illness and influenza-like syndrome, or may progress to an overwhelming pansystemic disease with hepatic and renal failure and hemorrhage caused by platelet and clotting abnormalities.^{100,106,115,} Yellow fever has an abrupt onset after an incubation period of 3–6 days.^{100,106,} Symptoms include fever, malaise, prostration, headache, photophobia, generalized arthralgia and myalgia, nausea and/or vomiting.^{106,} Humans infected with yellow fever virus experience the highest levels of viremia and can transmit the virus to mosquitoes shortly before onset of fever and for the first 3–5 days of illness.^{100,101,115,}

Yellow fever vaccine is prepared by culturing the 17D-204 strain of yellow fever virus in living avian leukosis virus-free (ALV-free) chicken embryos.^{106,} The vaccine contains sorbitol and gelatin as a stabilizer, is lyophilized, and is hermetically sealed under nitrogen.^{106,} No preservative is added.^{106,} The vaccine is formulated to contain not less than 4.74 log₁₀ plaque forming units (PFU) per 0.5 mL dose throughout the life of the product.^{106,}

Vaccination with yellow fever vaccine containing live, attenuated strains of the 17D strain of yellow fever virus is predicted to produce an immune response similar to that induced by infection with wild-type yellow fever virus.^{106,} Following administration of yellow fever vaccine, initial infection with the vaccine virus occurs in the cells in the dermis or other subcutaneous tissues near the injection site.^{106,} Subsequently, replication and limited spread of the virus leads to the processing and presentation of viral antigens to the immune system, similar to what would occur during infection with wild-type yellow fever virus.^{106,} The humoral immune response to the structural proteins of the vaccine virus can be detected by formation of specific antibodies that are detected as neutralizing antibodies in assays that measure the ability of serum to reduce plaque formation in tissue culture cells.^{106,}

The minimum titer of anti-yellow fever neutralizing antibodies conferring protection against yellow fever has not been definitively established to date.^{100,106,} WHO considers a log₁₀ neutralization index of 0.7 or greater measured by plaque reduction assay to be indicative of an adequate response to yellow fever vaccine and this was the level used to define seroconversion in clinical trials of the vaccine.^{106,}

Immunity to yellow fever generally develops within about 10 days following primary immunization with a single subcutaneous dose of yellow fever vaccine and for most healthy individual provides long-lasting protection.^{106,}

Advice to Patients

The following information contains important points for the clinician to discuss with patients during counseling. For more comprehensive monographs suitable for distribution to the patient, please refer to the *AHFS Patient Medication Information* monographs available from [MedlinePlus](#) (in English and Spanish; written at a 6th- to 8th-grade reading level).

- Inform the patient and/or the patient's parent or guardian of the benefits and risks of vaccination with yellow fever vaccine and provide a copy of the appropriate Vaccine Information Statement (available at CDC website at [\[Web\]](#)).^{106,112,}
- Inform patients and/or the patient's parent or guardian to report any severe or unusual adverse reactions that occur up to 30 days after vaccination to their healthcare provider.^{106,} Clinicians or individuals can report any adverse reactions that occur following vaccination to VAERS at 800-822-7967 or [\[Web\]](#) .^{100,106,} Adverse reactions to the vaccine also should be reported to the manufacturer.^{106,}
- Advise patients and/or patient's parent or guardian that yellow fever vaccine should not be used in individuals with life-threatening allergic reactions to eggs, egg products, or chicken protein, vaccine ingredients or packaging components (e.g., gelatin), or a previous dose of the vaccine.^{106,} Advise patients to inform the clinician of any history of sensitivity to egg or chicken protein since sensitivity testing may be necessary prior to vaccination.^{106,}
- Advise patients to inform clinicians if the patient has a weakened immune system (e.g., leukemia, lymphoma, HIV/AIDS, thymic disease) or is receiving treatment that may weaken the immune system (e.g., high-dose corticosteroids).^{106,}
- Advise patients and/or patient's parent or guardian that yellow fever vaccine is given only at certain vaccination centers authorized to issue valid International Certificates of Vaccination or Prophylaxis (ICVPs) and that the completed document will be needed as proof of vaccination before the individual is allowed to enter certain countries.^{100,106,115,} Current information regarding which countries are in yellow fever endemic zones and/or have vaccination requirements for entry is available at [\[Web\]](#) .^{115,}
- Advise patients and/or patient's parent or guardian that yellow fever vaccine may not provide protection in all vaccine recipients.^{106,} In addition to being vaccinated, advise patients to avoid exposure to mosquitoes while in yellow fever endemic areas (e.g., stay in air-conditioned or well-screened areas, wear long-sleeved shirts and long pants to cover the body, use appropriate insect repellents, use mosquito nets between dusk and dawn).^{116,}
- Advise patients of the signs and symptoms of an allergic reaction (e.g., urticaria, angioedema, rash, dyspnea, bronchospasm, pharyngeal edema, wheezing, throat tightness) and to immediately contact a clinician if any symptoms of an allergic reaction develop following vaccination.^{100,}
- Inform patients that vaccination certificates are valid commencing 10 days after vaccination.^{106,}
- Advise individuals ≥60 years of age that they may be at increased risk for adverse effects after receiving yellow fever vaccine compared with younger adults.^{106,}

- Advise patients with young children that yellow fever vaccine should not be generally used in infants <9 months of age and of the importance of avoiding yellow fever endemic areas if traveling with children in this age group.^{106,}
- Advise patients of the importance of informing clinicians of existing or contemplated concomitant therapy, including prescription and OTC drugs, as well as any concomitant illnesses.^{106,}
- Advise women to inform clinicians if they are or plan to become pregnant.^{106,} Advise such women that the vaccine should be used during pregnancy only when clearly needed and that efforts should be made to postpone travel to yellow fever endemic areas until after delivery.^{106,} If travel to yellow fever endemic areas cannot be avoided during pregnancy, discuss the risks and benefits of vaccination.^{106,}
- Advise women to inform clinicians if they plan to breast-feed.^{106,} Advise such women that the vaccine is not recommended for use in nursing women, particularly when breast-feeding infants are <9 months of age.^{106,}
- Advise patients of other important precautionary information.^{106,}

Additional Information

The American Society of Health-System Pharmacists, Inc. represents that the information provided in the accompanying monograph was formulated with a reasonable standard of care, and in conformity with professional standards in the field. Readers are advised that decisions regarding use of drugs are complex medical decisions requiring the independent, informed decision of an appropriate health care professional, and that the information contained in the monograph is provided for informational purposes only. The manufacturer's labeling should be consulted for more detailed information. The American Society of Health-System Pharmacists, Inc. does not endorse or recommend the use of any drug. The information contained in the monograph is not a substitute for medical care.

Preparations

Excipients in commercially available drug preparations may have clinically important effects in some individuals; consult specific product labeling for details.

In the US, yellow fever vaccine is supplied only to designated Yellow Fever Vaccination Centers authorized to issue valid International Certificates of Vaccination or Prophylaxis (ICVPs) for documentation of vaccination against yellow fever.^{100,106,115,} The US Centers for Disease Control and Prevention (CDC) yellow fever vaccination clinic search page at [\[Web\]](#) and state or local public health departments should be consulted for information regarding the location of these vaccination centers.^{100,106,115,}

Yellow Fever Vaccine

ROUTES	FORMS	STRENGTHS	BRAND NAMES	MANUFACTURER
Parenteral	For injection, for subcutaneous use	$\geq 4.74 \log_{10}$ plaque-forming units (PFU) per 0.5 mL	YF-VAX [®]	Sanofi Pasteur

† Use is not currently included in the labeling approved by the US Food and Drug Administration.

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