INFLUENZA VACCINE INACTIVATED

Influenza Vaccine Inactivated

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On January 5, 2026, the US Department of Health and Human Services (HHS) announced the approval of a revised US childhood and adolescent immunization schedule ([Web]). Under the revised recommendations, CDC continues to organize the childhood immunization schedule in three distinct categories (Immunizations Recommended for All Children, Immunizations Recommended for Certain High-Risk Groups or Populations, and Immunizations Based on Shared Clinical Decision-Making) but changes individual vaccine placement within those categories. For additional information, see [Web] .

Introduction

Influenza vaccine inactivated (IIV3) stimulates active immunity to influenza virus infection.[104,106,107,108,160,186,190] Influenza virus vaccine inactivated contains noninfectious, suitably inactivated influenza virus types A and B subunits representing influenza strains likely to circulate in the US during the upcoming influenza season.[104,106,107,108,160,186,190]

Uses

Prevention of Seasonal Influenza A and B Virus Infections

Influenza vaccine inactivated is used to stimulate active immunity for the prevention of disease caused by influenza virus subtypes A and B represented in the vaccine.[104,106,107,108,160,186,190] Several different preparations of influenza vaccine inactivated are commercially available in the US; these preparations differ based on dose (standard versus high dose), method of manufacturer (cell-based versus egg-based), and indicated population.[104,106,107,108,160,186,190] Although most inactivated influenza vaccines available in the US for use in adults and pediatric patients ≥6 months of age are egg-based vaccines (Afluria®, Fluarix®, Flulaval®, Fluzone®),[104,106,107,108] a cell culture-based vaccine (Flucelvax®) also is available for use in individuals ≥6 months of age.[190] In addition, an egg-based vaccine (Fluzone® High-Dose)[160] and adjuvant-containing egg-based vaccine (Fluad®)[186] are available for use in adults ≥65 years of age.

Each year, influenza vaccines are formulated based on recommendations from the FDA, Centers for Disease Control and Prevention (CDC), and other organizations.[100,101,102,112] All influenza vaccines available in the US for the 2025-26 season are trivalent formulations containing antigens representing influenza A (H1N1), influenza A (H3N2), and influenza B (Victoria lineage).[100,102]

Clinical Perspective

The American Academy of Pediatrics (AAP) and other organizations provide annual recommendations for the use of influenza vaccines in the US.[79,100,111,112] These organizations recommend annual influenza vaccination in *all* persons ≥6 months of age who do not have contraindications.[100,111,112] The Centers for Disease Control and Prevention (CDC) recommends the influenza vaccine for children after shared clinical decision-making with a healthcare provider.[591]

Various preparations of influenza virus vaccines are commercially available in the US, which differ based on method of manufacturer (egg-based versus cell culture-based), dose (standard versus high-dose), and route of administration (e.g., parenteral versus intranasal).[100] These preparations can be grouped into 3 broad categories: inactivated influenza vaccines (IIV3), recombinant influenza vaccine (RIV3), and live attenuated virus vaccine (LAIV3).[100] Inactivated influenza vaccines (IIV3) include standard-dose egg-based vaccines, a standard-dose cell culture-based influenza vaccine (ccIIV3), a high-dose egg-based vaccine (HD-IIV3), and an adjuvanted standard-dose egg-based vaccine

(aIIV3).[100] For the 2025–26 season, egg-based influenza vaccines available in the US (i.e., vaccines other than ccIIV3 and RIV3) contain hemagglutinin derived from an influenza A/Victoria/4897/2022 (H1N1)pdm09-like virus; an influenza A/Croatia/10136RV/2023 (H3N2)-like virus; and an influenza B/Austria/1359417/2021 (B/Victoria lineage)-like virus.[100] For the 2025–26 season, cell culture-based inactivated (ccIIV3) and recombinant (RIV3) influenza vaccines in the US contain hemagglutinin derived from an influenza A/Wisconsin/67/2022 (H1N1)pdm09-like virus; an influenza A/District of Columbia/27/2023 (H3N2)-like virus; and an influenza B/Austria/1359417/2021 (B/Victoria lineage)-like virus.[100]

ACIP states that all persons ≥6 months of age may receive an age-appropriate influenza vaccine with the exception of solid organ transplant recipients 18 through 64 years of age who are receiving immunosuppressive medication regimens; these individuals may receive either high-dose inactivated influenza vaccine (HD-IIV3) or adjuvanted inactivated influenza vaccine (aIIV3) as acceptable options (without a preference over other age-appropriate IIV3s or RIV3).[100] ACIP states that there are no preferential recommendations for any specific vaccine type when more than one licensed, recommended, and age-appropriate vaccine is available, with the exception of selection of influenza vaccines for individuals ≥65 years of age.[100] Because influenza vaccines are often less effective in older adults, the higher dose vaccines or adjuvanted vaccine is recommended in this population.[100] For the 2025-26 influenza season, ACIP recommends that adults ≥65 years preferentially receive trivalent high-dose inactivated influenza vaccine (HD-IIV3), trivalent recombinant influenza vaccine (RIV3), or trivalent adjuvanted inactivated influenza vaccine (aIIV3).[100] If none of these vaccines is available at an opportunity for vaccine administration, then any other age-appropriate influenza vaccine should be used.[100] Live attenuated influenza vaccine (LAIV3) should not be used in immunocompromised persons, persons with certain medical conditions, or persons receiving, having recently received, or about to receive influenza antiviral medications; LAIV also should not be used during pregnancy.[100] Patients should consult their healthcare provider about available flu vaccine options.[100]

The American College of Obstetricians and Gynecologists (ACOG) provides recommendations for annual influenza vaccine in pregnant individuals.[21] Because the risks associated with influenza infection are increased in both pregnant patients and their newborns,[21] ACOG recommends that individuals who are or will be pregnant during the influenza season receive an inactivated or recombinant influenza vaccine as soon as the vaccines are available.[21]

The Center for Infectious Disease Research and Policy (CIDRAP) has established the Vaccine Integrity Project to provide evidence-based guidance on vaccines.[22] The Vaccine Integrity Project is an initiative dedicated to providing trusted, science-based information for informed vaccine choices.[22] A multi-disciplinary group of experts was convened by the Vaccine Integrity Project to independently review the available data on vaccine efficacy, effectiveness, and safety of COVID-19, influenza, and RSV immunizations for the 2025-2026 respiratory virus season.[22] A systematic review of 511 published studies (mostly observational) was conducted.[18] Results of the evidence review found that influenza vaccination was effective against symptomatic infection and hospitalization across age groups; pooled vaccine effectiveness against hospitalization was 48% in adults 18-64 years of age and 67% in children.[18] The recommended high-dose formulations were associated with added benefit in older adults.[18] For additional information, see [Web] .

Regarding the timing of influenza vaccination, ACIP states that for most individuals who need only 1 dose of influenza vaccine for the season, the vaccine should ideally be offered during September or October.[100] However, vaccination should continue after October and throughout the influenza season as long as influenza viruses are circulating and unexpired vaccine is available.[100] For most adults, vaccination during July and August generally should be avoided unless there is a concern that vaccination during the season might not be possible; however, vaccination during these months can be considered in children who require 2 doses, children who require only 1 dose but visit their healthcare provider during late summer before the start of the school year, and pregnant persons in the third trimester.[100]

■ Other Influenza Virus Infections

Avian Influenza A Virus Infections

Influenza vaccines used for the prevention of seasonal influenza are *not* expected to provide protection against infection with avian influenza A viruses, including avian influenza A (H5N1).[149] Although not commercially available, several different inactivated influenza A (H5N1) monovalent vaccines have received FDA approval and are stored in the US Strategic National Stockpile (SNS).[469,472,473]

Avian influenza A virus refers to influenza A subtypes that occur mainly in birds but also have rarely caused infection in humans (H5N1, H5N6, H5N8, H7N2, H7N4, H7N3, H7N7, H7N9, H9N2, H10N8).[149,171] Experience to date indicates that avian influenza A viruses are not easily transmitted from wild or domestic birds, water fowl, or poultry to humans, but human infections can occur and have been linked to contact with live or dead infected birds or poultry, uncooked poultry products, or surfaces contaminated with infected poultry feces or respiratory secretions.[147,149,312,316,317,318,565]

The best way to prevent H5N1 bird flu is to avoid sources of exposure whenever possible.[149] Although seasonal influenza vaccines are not expected to provide protection against avian influenza A viruses, including avian influenza A (H5N1),[149] they might reduce the risk of coinfection and thereby reduce the theoretic potential for human-avian reassortment of genes in an individual simultaneously infected with a human and avian strain.[149]

Information regarding treatment and prevention of avian influenza A infections is available from CDC at [Web] and WHO at [Web] .

Dosage and Administration

■ General

Pretreatment Screening

- Screen all individuals for contraindications and precautions to vaccination.[100,112]

Patient Monitoring

- Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of influenza vaccine inactivated.[104,106,107,108,160,186,190]

Administration

Inactivated influenza vaccines are administered by IM injection; do not administer intradermally or subcutaneously.[104,106,107,108,160,186,190]

As an alternative to IM injection using a needle and syringe, Afluria® may be administered IM using a PharmaJet® Stratis® needle-free injection system *only* in adults 18 through 64 years of age.[108,543] Other commercially available inactivated influenza vaccines should *not* be administered IM using a jet injector.[543]

The vaccine product should be inspected visually for particulate matter and discoloration prior to administration.[104,106,107,108,160,186,190] Discard the vaccine if it contains particulates, appears discolored, or cannot be resuspended with thorough agitation.[104,106,107,160,190]

Influenza vaccine inactivated should *not* be mixed with any other vaccine or solution.[104,134,160,186,190]

Influenza vaccine inactivated should be stored at 2–8°C; do not freeze (if freezing occurs, discard vaccine).[104,106,107,108,160,186,190] Multiple-dose vials should be returned to 2–8ºC between uses.[104,108] The manufacturer of Afluria® states to discard any vaccine remaining in multiple-dose vials after a total of 20 doses has been removed from the vial and discard the multiple-dose vial if not used within 28 days after first entry.[108] The vaccine should be protected from light.[106,108,186,190] Single-dose vials are preservative-free.[104,106,107,108,160] Multiple-dose vials contain thimerosal as a preservative.[104,108,190]

Syncope (vasovagal or vasodepressor reaction; fainting) may occur following vaccination; such reactions occur most frequently in adolescents and young adults.[134] Take appropriate measures to decrease the risk of injury if a vaccine recipient becomes weak or dizzy or loses consciousness (e.g., vaccine recipients should sit or lie down during and for 15 minutes after vaccination).[134] If syncope occurs, observe the individual until symptoms resolve.[134]

Influenza vaccine inactivated may be administered concurrently with other vaccines during the same health-care visit.[134] When multiple vaccines are administered during a single health-care visit, each parenteral vaccine should be given using separate syringes 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]

IM Administration

Prefilled single-dose syringes containing influenza virus vaccine inactivated for IM administration should be shaken before administering the dose.[104,106,107,108,160,186,190]

Vials containing influenza virus vaccine inactivated for IM administration should be shaken before withdrawing a dose.[104,108,190]

Depending on patient age, IM injections should be made into the anterolateral muscles of the thigh or deltoid muscle of the arm.[134] Some clinicians recommend that infants and younger children be vaccinated in the anterolateral thigh because of the larger muscle mass than the deltoid.[134] In certain circumstances (e.g., physical obstruction at other sites and no reasonable indication to defer the vaccine dose), IM injections can be made into the gluteal muscle using care to identify anatomic landmarks prior to injection.[134]

In adults, adolescents, and children 3 years of age or older, IM injections should preferably be made into the deltoid muscle.[104,106,107,108,134,160,186,190]

To ensure delivery into muscle, IM injections should be administered at a 90° angle to the skin using a needle length appropriate for the individual's age and body mass, thickness of adipose tissue and muscle at the injection site, and injection technique.[134] Anatomic variability, especially in the deltoid, should be considered and clinical judgment should be used to avoid inadvertent underpenetration or overpenetration of muscle.[134]

Jet Injector (Afluria®)

Afluria® may be administered IM using a PharmaJet® Stratis® needle-free injection system in adults 18 through 64 years of age.[108] The jet injector should not be used to administer Afluria® in individuals younger than 18 years of age or geriatric adults ≥65 years of age.[108]

For specific information on how to administer Afluria® using the PharmaJet® Stratis® needle-free injection system, the manufacturer's information for the jet injector should be consulted.[108]

Dosage

Dose and dosing schedule (i.e., number of doses) of influenza virus vaccine inactivated for prevention of seasonal influenza depend on the individual's age, vaccination history, and specific product administered.[104,106,107,108,160,186,190]

Pediatric Dosage

Infants and Children 6 through 35 Months of Age (Afluria®)

If Afluria® is used for prevention of seasonal influenza in infants and children 6 through 35 months of age, reduced doses of 0.25 mL should be used.[100,108]

Infants and children 6 through 35 months of age who did not receive a total of 2 or more doses of any seasonal influenza vaccine before July 1, 2025 or whose previous influenza vaccination history is unknown: Administer 2 doses of Afluria® at least 4 weeks apart.[100,108] Each dose consists of 0.25 mL.[108]

Infants and children 6 through 35 months of age who received a total of 2 or more doses of any seasonal influenza vaccine ≥4 weeks apart before July 1, 2025: Administer a single 0.25 mL dose of Afluria®.[100,108]

Infants and Children 6 through 35 Months of Age (Fluarix®, Flulaval®)

For prevention of seasonal influenza in infants and children 6 through 35 months of age who did not receive a total of 2 or more doses of any seasonal influenza vaccine before July 1, 2025 or whose previous influenza vaccination history is unknown: Administer 2 doses of Fluarix® or Flulaval® at least 1 month (4 weeks) apart.[100] Each dose consists of 0.5 mL.[106,107]

In infants and children 6 through 35 months of age who received a total of 2 or more doses of any seasonal influenza vaccine ≥4 weeks apart before July 1, 2025, administer a single 0.5 mL dose of Fluarix® or Flulaval®.[100,106,107]

Infants and Children 6 through 35 Months of Age (Fluzone®)

If Fluzone® is used for prevention of seasonal influenza in infants and children 6 through 35 months of age, reduced doses (0.25 mL; prefilled syringes 0.25 mL no longer available) or standard doses (0.5 mL) may be used.[104]

For prevention of seasonal influenza in infants and children 6 through 35 months of age who did not receive a total of 2 or more doses of any seasonal influenza vaccine before July 1, 2025 or whose previous influenza vaccination history is unknown: The manufacturer recommends two 0.25-mL doses, two 0.5-mL doses, or one 0.25- and one 0.5-mL dose of Fluzone® administered at least 1 month (4 weeks) apart.[100,104]

In infants and children 6 through 35 months of age who received a total of 2 or more doses of any seasonal influenza vaccine ≥4 weeks apart before July 1, 2025, administer a single 0.25- or 0.5-mL dose of Fluzone®.[100,104]

Children 6 months through 8 Years of Age (Flucelvax®)

For prevention of seasonal influenza in children 6 months through 8 years of age who did not receive a total of 2 or more doses of any seasonal influenza vaccine before July 1, 2025 or whose previous influenza vaccination history is unknown: Administer 2 doses of Flucelvax® at least 1 month (4 weeks) apart.[100,190] Each dose consists of 0.5 mL.[190]

In children 6 months through 8 years of age who received a total of 2 or more doses of any seasonal influenza vaccine ≥4 weeks apart before July 1, 2025: Administer a single 0.5 mL dose of Flucelvax®.[100,190]

Children 3 through 8 Years of Age (Afluria®, Fluarix®, Flulaval®, Fluzone®)

In children 3 through 8 years of age who did not receive a total of 2 or more doses of any seasonal influenza vaccine before July 1, 2025 or whose previous influenza vaccination history is unknown: Administer 2 doses of Afluria®, Fluarix®, Flulaval®, or Fluzone® at least 1 month (4 weeks) apart.[100,104,106,107,108] Each dose consists of 0.5 mL.[104,106,107,108]

In children 3 through 8 years of age who received a total of 2 or more doses of any seasonal influenza vaccine 4 weeks apart before July 1, 2025, administer a single 0.5 mL dose of Afluria®, Fluarix®, Flulaval®, or Fluzone®.[100,104,106,107,108]

Children and Adolescents 9 through 17 Years of Age (Afluria®, Fluarix®, Flucelvax®, Flulaval®, Fluzone®)

For prevention of seasonal influenza infection in children and adolescents 9 through 17 years of age, 0.5 mL of Afluria®, Fluarix®, Flucelvax®, Flulaval®, or Fluzone® should be administered IM as a single dose.[100,104,106,107,108,190]

Adult Dosage

Adults 18 Years of Age or Older (Afluria®, Fluarix®, Flucelvax®, Flulaval®, Fluzone®)

The usual dosage of Afluria®, Fluarix®, Flucelvax®, Flulaval®, or Fluzone® for prevention of seasonal influenza infection in adults 18 years of age or older is 0.5 mL administered IM as a single dose.[100,104,106,107,108,190]

Adults 65 Years of Age or Older (Fluad®, Fluzone® High-Dose)

The usual dosage of Fluad® standard-dose adjuvant-containing vaccine for prevention of seasonal influenza infection in adults 65 years of age or older is 0.5 mL administered IM as a single dose.[186]

The usual dosage of Fluzone® High-Dose for prevention of seasonal influenza infection in adults 65 years of age or older is 0.5 mL administered IM as a single dose.[160]

Special Populations

Hepatic Impairment

The manufacturers make no specific dosage recommendations for patients with hepatic impairment.[104,106,107,108,160,186,190]

Renal Impairment

The manufacturers make no specific dosage recommendations for patients with renal impairment.[104,106,107,108,160,186,190]

Geriatric Patients

For dosing in geriatric patients, see dosage recommendations for adults based on age.[104,106,107,108,160,186,190]

Cautions

Contraindications

- History of severe hypersensitivity (e.g., anaphylaxis) to previous dose of any influenza vaccine.[104,106,107,108,160,186]
- Egg-based influenza vaccine inactivated: History of severe hypersensitivity (e.g., anaphylaxis) to any component of the vaccine, including egg protein.[104,106,107,108,160,186]
- Cell culture-based influenza vaccine inactivated: History of severe allergic reactions (e.g., anaphylaxis) to any component of the vaccine.[190]

Warnings/Precautions

Hypersensitivity Reactions

Allergic or immediate hypersensitivity reactions (e.g., urticaria, angioedema, anaphylaxis, anaphylactic shock, serum sickness, allergic asthma) have been reported rarely.[104,106,107,108] Prior to administration, review patient's history with respect to possible sensitivity reactions to the vaccine or vaccine components, including egg protein, and prior vaccination-related adverse effects and assess benefits versus risks.[106,107,108] Administer influenza vaccine inactivated in a setting where appropriate medical treatment and supervision are available to manage possible anaphylactic reactions if they occur.[104,106,107,108,134,160,186,190]

Most seasonal inactivated influenza vaccines (Afluria®, Fluad®, Fluarix®, Flulaval®, Fluzone®) are produced using embryonated chicken eggs; these vaccines can contain residual egg protein (ovalbumin).[104,106,107,108,160,186] Manufacturers of egg-based inactivated influenza vaccines state that these vaccines are contraindicated in individuals who have had a severe allergic reaction (e.g., anaphylaxis) to egg protein.[104,106,107,108,160,186] ACIP states that all individuals ≥6 months of age with egg allergy should receive influenza vaccine with any influenza vaccine (egg-based or nonegg-based) that is otherwise appropriate for the recipient's age and health status.[100] Egg allergy alone necessitates no additional safety measures for influenza vaccination beyond those recommended for any recipient of any vaccine, regardless of severity of previous reaction to egg.[100] Although egg allergy is neither a contraindication nor precaution to the use of any influenza vaccine, there are contraindications and precautions related to allergies to vaccine components, including egg protein, or following a previous administration of any influenza vaccine.[100,104,106,107,108]

Some preparations of influenza vaccine inactivated (e.g., Afluria®, Fluad®) contain trace amounts of neomycin, although allergies to neomycin are rare.[108,134,186] Neomycin hypersensitivity usually manifests as a delayed-type (cell-mediated) contact dermatitis.[134] ACIP states that a history of delayed-type allergic reaction to neomycin is not a contraindication to the use of vaccines containing trace amounts of neomycin; however, it is recommended that individuals with a history of anaphylactic reaction to neomycin be evaluated by an allergist prior to receiving a neomycin-containing vaccine.[134]

Some multi-dose vials of influenza vaccine inactivated (Afluria®, Flucelvax®, Fluzone®) contain trace amounts of thimerosal, a mercury derivative, as a preservative.[104,108,134,190] Hypersensitivity reactions to thimerosal contained in vaccines have been reported in some individuals.[140,498,500] These reactions usually manifest as local, delayed-type hypersensitivity reactions (e.g., erythema, swelling), but a generalized reaction manifested as pruritus and an erythematous, maculopapular rash on all 4 extremities has been reported rarely.[134,140,427,500] ACIP states that a history of local or delayed-type hypersensitivity to thimerosal is not a contraindication to use of vaccines that contain thimerosal.[134]

Guillain-Barré Syndrome (GBS)

If GBS occurred within 6 weeks after previous influenza vaccination, manufacturers state to base decision to administer influenza vaccine on careful consideration of potential benefits and risks.[104,106,107,108,160,186,190] The 1976 swine influenza vaccine was associated with increased frequency of GBS. Evidence for causal relationship between other influenza vaccines and GBS is inconclusive; if an excess risk exists, it is probably slightly more than 1 additional case of GBS per 1 million vaccinees.[104,106,107,108,160,186,190]

ACIP states that a history of GBS within 6 weeks after receipt of any influenza vaccine is a precaution to the use of all influenza vaccines.[100]

Individuals with Altered Immunocompetence

If influenza vaccine inactivated is administered to immunosuppressed individuals, consider the possibility that the immune response may be lower than in immunocompetent individuals.[104,106,107,108,160,186,190]

ACIP states that all non-live vaccines can be administered safely to individuals with altered immunocompetence.[134]

Individuals with Bleeding Disorders

Advise individuals and/or their family about the risk of hematoma from IM injections.[134]

ACIP states that vaccines may be given IM to such individuals if a clinician familiar with the patient's bleeding risk determines that the preparation can be administered with reasonable safety.[134] In these cases, use a fine needle (23-gauge or smaller) to administer the vaccine and apply firm pressure to the injection site (without rubbing) for ≥2 minutes.[134] In individuals receiving therapy for hemophilia, IM vaccines can be scheduled for administration shortly after a dose of such therapy.[134]

Concomitant Illnesses

The decision to administer or delay vaccination in an individual with a current or recent acute illness should be based on the severity of symptoms and etiology of the illness.[134]

ACIP states that mild acute illness does not preclude vaccination.[134] Moderate or severe acute illness (with or without fever) is a precaution for vaccination; defer vaccines until the individual has recovered from the acute phase of the illness.[134] This avoids superimposing vaccine adverse effects on the underlying illness or mistakenly concluding that a manifestation of the underlying illness resulted from vaccine administration.[134]

Limitations of Vaccine Effectiveness

Influenza vaccine inactivated may not protect all vaccine recipients against influenza.[104,106,107,108,160,186,190]

Syncope

Syncope has been reported following vaccination with inactivated influenza vaccines; implement procedures to avoid injury from fainting.[104,106,107,108,160,186,190]

Specific Populations

Pregnancy

Data collected in a prospective pregnancy exposure registry from women vaccinated with influenza virus vaccine inactivated quadrivalent (Afluria®, Fluarix®, Flucelvax®) found no evidence of a vaccine-associated increase in the risk of major birth defects and miscarriages when administered during any trimester of pregnancy.[106,108,190] Data for quadrivalent vaccines are relevant to trivalent products because both vaccines are manufactured using the same process and have overlapping compositions.[106,107,108] Data are insufficient to assess the risk of use during pregnancy for other inactivated influenza vaccines (Fluzone®, Fluad®, Flulaval®).[104,107,160,186]

Animal reproduction studies have not revealed evidence of harm to a fetus.[104,106,107,108,160,186,190] Pregnant and postpartum women are at higher risk for severe influenza and influenza-related complications, particularly during the second and third trimesters, which may lead to adverse pregnancy outcomes including preterm labor and delivery.[104,106,107,190]

To monitor pregnancy outcomes and newborn health status following influenza vaccination of pregnant women, some manufacturers have established pregnancy registries.[104,106,107,190]

Lactation

It is not known whether influenza vaccine inactivated is distributed into human milk.[104,106,107,108,160,186,190] Data are insufficient to assess effects on the breast-fed infant or on milk production.[104,106,107,108,160,186,190] Consider the benefits of breast-feeding and importance of the vaccine to the woman; also consider potential adverse effects on the breast-fed child from the vaccine or underlying maternal condition (i.e., susceptibility to influenza infection).[104,106,107,108,160,186,190]

ACIP states that breast-feeding is not a contraindication to influenza vaccine inactivated; the vaccines do not pose any unusual risks for the mother or her nursing infant.[134]

Pediatric Use

Afluria®, Fluarix®, Flulaval®, Fluzone®, Flucelvax®: Safety and efficacy not established in infants <6 months of age.[104,106,107,108]

Fluad® adjuvant-containing: Safety and efficacy not established in pediatric patients.[186]

Fluzone® High-Dose: Safety and efficacy not established in pediatric patients.[160]

Geriatric Use

Afluria®, Fluarix®, Flucelvax®, Flulaval®, Fluzone®: No overall differences in safety relative to younger adults;[104,106,107,190] may be less immunogenic in geriatric individuals.[108,190]

Fluad® adjuvant-containing: Use only in adults ≥65 years of age.[186]

> *Fluzone® High-Dose: Use in adults ≥65 years of age.[160] Each 0.5 mL of Fluzone® High-Dose contains 4 times the amount of antigen contained in standard-dose Fluzone®.[160] In adults ≥65 years of age, higher incidence of injection site reactions and systemic adverse effects reported with Fluzone® High-Dose compared with standard-dose Fluzone®.[100] Some evidence that the high-dose formulation elicits higher antibody titers and higher seroconversion rates than the standard-dose formulation in adults ≥65 years of age and may be more effective in preventing laboratory-confirmed influenza in this age group.[100]*
>
> *ACIP states that all adults ≥65 years of age should be vaccinated against influenza using influenza virus vaccine inactivated or influenza vaccine recombinant.[100] ACIP states a preference for Fluzone® High-Dose, Flublok® recombinant influenza vaccine, or the standard-dose adjuvant-containing vaccine (Fluad®), but if none of these 3 vaccines is available at the time of vaccine administration, then adults ≥65 years may receive a standard-dose preparation.[100]*

Common Adverse Effects

The most common adverse effects of influenza vaccine inactivated are listed below for individual vaccine preparations.

Fluzone

In children 6 months through 8 years of age, the most common injection-site adverse reactions were pain or tenderness (>50%) and redness (>25%); the most common solicited systemic adverse reactions were irritability and drowsiness (>25% of children 6 months through 35 months) and myalgia (>20% of children 3 years through 8 years).[104]

In adults 18 through 64 years of age, the most common injection-site adverse reaction was pain (>50%); the most common solicited systemic adverse reactions were headache and myalgia (>30%).[104]

In adults ≥65 years of age, the most common injection-site adverse reaction was pain (>20%); the most common solicited systemic adverse reactions were headache, myalgia, and malaise (>10%).[104]

Fluarix

In adults, the most common (≥10%) solicited local adverse reactions were pain and redness; the most common systemic adverse reactions were muscle aches, fatigue, and headache.[106]

In children 5 through 17 years of age, the most common (≥10%) solicited local adverse reactions were pain, redness, and swelling; the most common systemic adverse reactions were muscle aches, fatigue, and headache.[106]

In children 3 through 4 years of age, the most common (≥10%) solicited local adverse reactions were pain, redness, and swelling; the most common systemic adverse reactions were irritability, loss of appetite (13%), and drowsiness.[106]

In children 6 through 35 months of age who received Fluarix QUADRIVALENT, the most common (≥10%) solicited local adverse reactions were pain and redness; the most common systemic adverse reactions were irritability, loss of appetite, and drowsiness.[106]

Flulaval

In adults, the most common (≥10%) solicited local adverse reactions were pain, redness, and swelling; the most common solicited systemic adverse reactions were fatigue, headache, and muscle aches/arthralgia.[107]

In children 3 through 17 years of age, the most common (≥10%) solicited local adverse reaction was pain.[107]

In children 3 through 4 years of age, the most common (≥10%) solicited systemic adverse reactions were irritability, drowsiness, and loss of appetite.[107]

In children 5 through 17 years of age, the most common (≥10%) solicited systemic adverse reactions were muscle aches, headache, and fatigue.[107]

In children 6 through 35 months of age who received Flulaval QUADRIVALENT, the most common (≥10%) solicited local adverse reaction was pain; most common solicited systemic adverse reactions were irritability, drowsiness, and loss of appetite.[107]

Afluria

In adults 18 through 64 years, the most commonly reported injection-site adverse reaction was pain (≥40%).[108] The most common systemic adverse reactions were myalgia and headache (≥20%).[108]

In adults 65 years of age and older, the most commonly reported injection-site adverse reaction was pain (≥20%).[108] The most common systemic adverse reaction was myalgia (≥10%).[108]

In children 6 through 35 months of age, the most commonly reported injection-site reactions were pain and redness (≥20%).[108] The most common systemic adverse reactions were irritability (≥30%), diarrhea, and loss of appetite (≥20%).[108]

In children 36 through 59 months of age, the most commonly reported injection-site reactions were pain (≥30%) and redness (≥20%).[108] The most commonly reported systemic adverse reactions were malaise, fatigue, and diarrhea (≥10%).

In children 5 through 8 years of age, the most commonly reported injection-site adverse reactions were pain (≥50%), redness, and swelling (≥10%). The most common systemic adverse reaction was headache (≥10%)

In children 9 through 17 years, the most commonly reported injection-site adverse reactions were pain (≥50%), redness, and swelling (≥10%).[108] The most common systemic adverse reactions were headache, myalgia, malaise, and fatigue (≥10%).[108]

In adults 18 through 64 years of age receiving the PharmaJet Stratis needle-free injection system, the most commonly reported injection-site adverse reactions were tenderness (≥80%), swelling, pain, redness (≥60%), itching (≥20%), and bruising (≥10%).[108] The most common systemic adverse reactions were myalgia, malaise (≥30%), and headache (≥20%).[108]

Fluzone High-Dose

In adults ≥65 years of age, the most common (>10%) injection-site adverse reaction was pain; the most common solicited systemic adverse reactions were myalgia, malaise, and headache.[160]

Fluad

The most common (≥10%) local and systemic adverse reactions in adults ≥65 years of age were injection site pain, injection site tenderness, myalgia, fatigue, and headache.[186]

Flucelvax

In children 6 months through 3 years of age who received FLUCELVAX QUADRIVALENT, the most commonly reported injection-site adverse reactions were tenderness (28%), erythema (26%), induration (17%), and ecchymosis (11%).[190] The most common systemic adverse reactions were irritability (28%), sleepiness (27%), diarrhea (18%), and change of eating habits (17%).[190]

In children 4 through 8 years of age, the most commonly reported local injection-site adverse reactions were pain (29%) and erythema (11%).[190] The most common systemic adverse reaction was fatigue (10%).[190]

In children and adolescents 9 through 17 years of age, the most commonly reported injection-site adverse reactions were pain (34%) and erythema (14%).[190] The most common systemic adverse reactions were myalgia (15%) and headache (14%).[190]

In adults 18 through 64 years of age, the most commonly reported injection-site adverse reactions were pain (28%) and erythema (13%).[190] The most common systemic adverse reactions were headache (16%), fatigue (12%), myalgia (11%), and malaise (10%).[190]

In adults ≥65 years of age, the most commonly reported injection-site reaction was erythema (10%).[190] The most common systemic adverse reactions were fatigue (11%), headache (10%), and malaise (10%).[190]

Drug Interactions

■ Antiviral Agents

Antiviral agents used for the treatment or prevention of influenza (e.g., baloxavir marboxil, oseltamivir, peramivir, zanamivir) have no effect on the immune response to inactivated vaccines, including influenza vaccine inactivated.[134] Influenza vaccine inactivated may be administered to individuals receiving these antiviral drugs.[100]

■ Immunosuppressive Agents

Individuals receiving immunosuppressive therapy (e.g., alkylating agents, antimetabolites, certain biologic response modifiers, corticosteroids, radiation therapy) may have reduced immune responses to vaccines, including influenza virus vaccine inactivated.[104,106,107,108,134,160,186,190]

Inactivated vaccines generally should be administered at least 2 weeks prior to initiation of immunosuppressive therapy and, because of possible suboptimal response, should not be administered during and for certain periods of time after immunosuppressive therapy is discontinued. [134]

Inactivated vaccines should be administered at least 2 weeks prior to treatment with anti-B-cell antibodies (e.g., rituximab).[134] Some experts state that administration of inactivated vaccines should be deferred until at least 6 months after treatment with anti-B-cell antibodies has been discontinued. [134]

Inactivated vaccines should be administered at least 2 weeks prior to initiation of therapy with certain other immunosuppressive biologic response modifiers (e.g., colony-stimulating factors, interleukins, tumor necrosis factor [TNF; TNF-α] blocking agents).[134]

Corticosteroids given in greater than physiologic doses may reduce immune responses to vaccines.[134] AAP states that inactivated vaccines preferably should be administered at least 2 weeks prior to initiation of corticosteroid therapy that is considered immunosuppressive.[134]

■ Vaccines

Concurrent administration of influenza vaccine inactivated with other age-appropriate vaccines, including live virus vaccines, toxoids, or inactivated or recombinant vaccines, during the same health-care visit is not expected to affect immunologic responses or adverse reactions to any of the preparations.[134]

Immunization with influenza vaccine inactivated can be integrated with immunization against diphtheria, tetanus, pertussis, *Haemophilus influenzae* type b (Hib), hepatitis A, hepatitis B, human papillomavirus (HPV), measles, mumps, rubella, meningococcal disease, pneumococcal disease, poliomyelitis, rotavirus, and varicella.[134] However, each parenteral vaccine should be administered using separate syringes and different injection sites.[134]

An interim analysis of a clinical study of 296 persons ≥65 years of age comparing concomitant administration of a quadrivalent inactivated influenza vaccine (HD-IIV4) and a booster dose of an mRNA COVID-19 vaccine (administered in separate upper arm sites) with administration of either vaccine alone did not identify any safety concerns or any evidence of immune interference on influenza hemagglutination inhibition or SARS-CoV-2 binding antibody responses.[589] Local reactogenicity up to 21 days postvaccination was similar between the coadministration group and the group that received the mRNA COVID-19 vaccine alone.[589] Similar frequency of systemic reactions were reported in the coadministration and mRNA groups, but with lower frequencies observed in participants who received HD-IIV4 alone.[589]

In a multicenter, randomized clinical study, 679 adult participants were recruited to receive concomitant administration of either an age-appropriate influenza vaccine or placebo along with their second dose of a COVID-19 vaccine (either an adenovirus viral vector COVID-19 vaccine or an mRNA COVID-19 vaccine).[590] Injections were administered by IM injection in the upper arm, with one injection on each side for the concomitant administration recipients.[590] Analysis up to 21 days after vaccination, did not identify safety concerns or evidence of immune interference on influenza hemagglutination inhibition or SARS-CoV-2 binding antibody responses.[590] The study found similar rates of local reactogenicity between the coadministration group and single vaccine administration group; however, systemic reactions were reported at similar frequencies in the coadministration and mRNA vaccine groups, with lower frequencies observed in participants who received influenza vaccine alone.[590]

■ Zoster Vaccines

Data from an open-label, randomized study in adults 50 years of age or older indicate that concurrent administration of quadrivalent influenza virus vaccine inactivated (Fluarix®) and zoster vaccine recombinant (Shingrix®) does not interfere with the immune response to either vaccine[106,117] and is not associated with any safety concerns.[117] Although the rates of solicited systemic adverse effects (i.e., fatigue, headache, myalgia, shivering, fever) in those receiving the vaccines concurrently were similar to those observed when zoster vaccine recombinant was given alone, the rates were higher than those observed when quadrivalent influenza virus vaccine inactivated was given alone.[106]

Safety and efficacy of concomitant or sequential administration of adjuvant-containing influenza virus vaccine inactivated (Fluad®) and zoster vaccine recombinant have not been evaluated.[117]

Description

Inactivated influenza vaccines are noninfectious, sterile suspensions of suitably inactivated influenza virus types A and B subunits.[104,106,107,108,190] Influenza virus vaccines stimulate active immunity to influenza virus infection by inducing production of specific antibodies; protection is provided only against those strains of virus from which the vaccines are prepared and possibly closely related strains.[100] In healthy young adults, seasonal influenza virus vaccine inactivated has been shown to induce rapidly and simultaneously both a systemic (i.e., in serum)[159,222,252,253,254] and, to a lesser extent, local (i.e., in the upper respiratory tract)[222] immune response.

Local mucosal immunity in the respiratory tract (e.g., in tonsils) confers the initial line of defense against influenza.[222,252,253,254] It has been suggested that migration of activated B cells, particularly IgA-committed B cells, via lymphatic drainage from the injection site to the mucosal surfaces of the tonsils is responsible for the local immune response after influenza vaccination.[222]

Seasonal influenza vaccines are formulated annually to contain antigens representative of the strains of influenza A (H1N1), influenza A (H3N2), and influenza B viruses likely to circulate in the US during the upcoming influenza season.[100] All inactivated influenza vaccines (egg- or cell culture-based) currently available in the US are trivalent vaccines containing 2 influenza type A antigens (H1N1 and H3N2) and an influenza type B antigen (B/Victoria lineages).[100]

Although postvaccination antibody titers initially may remain stable (e.g., hemagglutination-inhibition [HI], IgG) or decrease (e.g., IgA) with repeated annual vaccination against seasonal influenza, prevaccination titers of HI, IgG, and IgA prior to the subsequent annual dose are increased overall.[380] Thus, repeated annual vaccination against seasonal influenza results in an increase in and maintenance of antibodies to seasonal influenza A (H1N1) and (H3N2) strains over time, which is beneficial for protection of vaccinees.[380] Even in individuals in whom a decrease in antibody titers occurs with repeated vaccination, an increase in avidity of the antibodies for influenza antigens could prevent a decline in immune competence.[380]

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).

- Prior to administration of seasonal influenza vaccine inactivated, provide a copy of the appropriate CDC Vaccine Information Statement (VIS) to the patient or patient's legal representative.[20,104,106,107,108,160,186,190]
- Advise patient and/or patient's parent or guardian of the risks and benefits of vaccine administration.[104,106,107,108,160,186,190]
- Advise patients that influenza vaccine inactivated contains noninfectious killed viruses and cannot cause influenza.[104,106,107,108,160,186,190]
- Advise patients that influenza vaccine inactivated provides protection against illness due to influenza viruses represented in the vaccine and cannot provide protection against all respiratory illness.[104,106,107,108,160,186,190]

- Stress importance of informing clinicians of severe or unusual adverse effects. [104,106,107,108,160,186,190,] Clinicians or individuals can report any adverse reactions that occur following vaccination to the Vaccine Adverse Event Reporting System (VAERS) at 800-822-7967 or [Web] . [104,106,107,108,160,186,190,]
- Stress importance of informing clinician of existing or contemplated concomitant therapy, including prescription and OTC drugs, as well as concomitant illnesses (e.g., GBS).[104,106,107,108,160,186,190,]
- Stress importance of patients informing clinicians if they are or plan to become pregnant or plan to breast-feed.[104,106,107,108,160,186,190,]
- Inform patients of other important precautionary information.[104,106,107,108,160,186,190,]

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.

Influenza Virus Vaccine Inactivated

ROUTES	FORMS	STRENGTHS	BRAND NAMES	MANUFACTURER
Parenteral	*Injectable suspension, for IM use*	*15 mcg hemagglutinin each of FDA-specified influenza A (H1N1), influenza A (H3N2), and influenza B/Victoria lineage antigens per 0.5 mL*	*Afluria 2025-2026 Formula®*	*Seqirus*
		15 mcg hemagglutinin each of FDA-specified influenza A (H1N1), influenza A (H3N2), and influenza B/Victoria lineage antigens per 0.5 mL	*Fluarix 2025-2026 Formula®*	*GlaxoSmithKline*
		15 mcg hemagglutinin each of FDA-specified influenza A (H1N1), influenza A (H3N2), and influenza B/Victoria lineage antigens per 0.5 mL	*Flucelvax 2025-2026 Formula®*	*Seqirus*
		15 mcg hemagglutinin each of FDA-specified influenza A (H1N1), influenza A (H3N2), and influenza B/Victoria lineage antigens per 0.5 mL	*Flulaval 2025-2026 Formula®*	*GlaxoSmithKline*
		15 mcg hemagglutinin each of FDA-specified influenza A (H1N1), influenza A (H3N2), and influenza B/Victoria lineage antigens per 0.5 mL	*Fluzone 2025-2026 Formula®*	*Sanofi Pasteur*
		60 mcg hemagglutinin each of FDA-specified influenza A (H1N1), influenza A (H3N2), and influenza B/Victoria lineage antigens per 0.5 mL	*Fluzone High-Dose 2025-2026 Formula®*	*Sanofi Pasteur*

Influenza Virus Vaccine Inactivated, Adjuvant-containing

ROUTES	FORMS	STRENGTHS	BRAND NAMES	MANUFACTURER

Parenteral	*Injectable emulsion, for IM use*	*15 mcg hemagglutinin each of FDA-specified influenza A (H1N1), influenza A (H3N2), and influenza B/Victoria lineage, antigens per 0.5 mL*	*Fluad 2025-2026 Formula®*	*Seqirus*

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

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