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Influenza Vaccine for 2024-2025

Annual vaccination in the US against influenza A and B viruses is recommended for everyone ≥6 months old without a contraindication.[1,2] Influenza vaccines available in the US for the 2024-2025 season are listed in Table 2.

COMPOSITION — All influenza vaccines available in the US this season are trivalent: they contain two influenza A virus antigens and one influenza B virus antigen (see Table 1).[3] Influenza A viruses are the primary cause of influenza-related morbidity and mortality, especially in older adults. Illness caused by influenza B viruses is usually more severe in children, especially those <5 years old.[4]

Table 1. 2024-2025 Influenza Vaccine Composition[1]

Egg-Based Vaccines
A/Victoria/4897/2022 (H1N1)pdm09-like
A/Thailand/8/2022 (H3N2)-like
B/Austria/1359417/2021 (Victoria lineage)-like
Cell Culture-Based and Recombinant Vaccines
A/Wisconsin/67/2022 (H1N1)pdm09-like
A/Massachusetts/18/2022 (H3N2)-like
B/Austria/1359417/2021 (Victoria lineage)-like

1. All influenza vaccines available in the US for the 2024-2025 influenza season are trivalent. B/Yamagata lineage viruses, the second influenza B virus strain included in quadrivalent vaccines in recent years, have not circulated since March 2020.

TIMING — In the US, vaccination against influenza should ideally be offered in September or October and continue to be offered as long as influenza viruses are circulating in the community. In most adults, serum antibody levels peak 1-2 weeks after vaccination. Vaccination in July or August may result in suboptimal immunity before the end of the influenza season, especially in adults ≥65 years old.[5]

The CDC Advisory Committee on Immunization Practices (ACIP) recommends that pregnant women who are in their first or second trimester during July or August delay vaccination, if possible, until September or October to ensure that their babies are protected throughout the influenza season. Vaccination during July or August can be considered for women who are in their third trimester.[1]

Key Points: Influenza Vaccine for 2024-2025

- Annual vaccination against influenza is recommended for everyone in the US ≥6 months old without a contraindication.
- Vaccination should ideally be offered in September or October and continue to be offered as long as influenza viruses are circulating in the community.
- All influenza vaccines available in the US this season are trivalent; they contain two influenza A virus antigens and one influenza B virus antigen.
- Influenza vaccination reduces the incidence of laboratory-confirmed influenza and the risk of serious complications and death associated with influenza illness.
- The ACIP preferentially recommends that adults ≥65 years old receive a high-dose, adjuvanted, or recombinant vaccine.
- Pregnant women should be vaccinated against influenza.
- The ACIP states that persons with a history of egg allergy can receive any age-appropriate influenza vaccine. Additional safety measures are no longer recommended for this patient population.

Children aged 6 months through 8 years who previously received two lifetime doses of an influenza vaccine will only need one dose this season. Those who require 2 doses should receive the first dose as early as possible so that the second dose can be given by the end of October (see Table 2, footnote 3). Vaccination in September or October is preferred for children of any age who need only one dose, but administration in July or August can be considered.

EFFECTIVENESS — Influenza vaccination reduces the incidence of laboratory-confirmed influenza and the risk of serious complications and death associated with influenza illness.[6-10] The effectiveness of the seasonal influenza vaccine in preventing influenza illness depends on several factors, including the match between the vaccine and circulating strains and the immunologic response of the recipient. Vaccine effectiveness is greatest when the match is close, but even when it is suboptimal, vaccination can substantially reduce the risk of influenza-related hospitalization and death.[11-13] In an observational study in 1,630,328 adults 18-64 years old, the high-dose recombinant vaccine (*Flubok Quadrivalent*) was significantly more effective than standard-dose vaccines in preventing influenza illness, but not influenza-related hospitalization.[14]

During the 2023-2024 influenza season in the Southern Hemisphere, vaccination was associated with a 52% reduction in the risk of influenza-associated hospitalization.[15]

OLDER ADULTS — Older adults are at increased risk for severe influenza illness, hospitalization, and death. Their immunogenic response to influenza vaccination may be reduced compared to that in younger persons, and their antibody levels may decline more rapidly.[16]

In a cohort study of hospitalized adults ≥60 years old with cardiovascular disease, influenza vaccination was associated with a reduced risk of recurrent hospitalization for ischemic heart disease, respiratory hospitalization, and in-hospital death.[17]

High-Dose Vaccine – *Fluzone High-Dose*, an inactivated vaccine that contains 4 times the amount of antigen included in standard-dose inactivated influenza vaccines, is FDA-licensed for use in persons ≥65 years old.

In a randomized, double-blind trial in a total of 31,989 adults ≥65 years old during 2 influenza seasons, *Fluzone High-Dose* induced significantly greater antibody responses than a standard-dose inactivated trivalent vaccine and was 24% more effective in preventing laboratory-confirmed influenza illness.[18] In observational studies and randomized trials in adults ≥65 years old, use of a high-dose inactivated vaccine was associated with a reduced risk of respiratory-related and all-cause hospitalization and death compared to use of a standard-dose inactivated vaccine.[19-23]

In patients with high-risk cardiovascular disease (recent MI or hospitalization for heart failure), use of a high-dose inactivated vaccine elicited greater humoral responses compared to standard-dose inactivated vaccines, but it did not significantly reduce all-cause mortality or cardiopulmonary hospitalizations.[24,25]

Adjuvanted Vaccine – *Fluad*, an adjuvanted inactivated influenza vaccine, is FDA-licensed for use in persons ≥65 years old. It contains MF59, an oil-in-water emulsion of squalene oil that increases the immune response by recruiting antigen-presenting cells to the injection site and promoting uptake of influenza virus antigens.

In a randomized trial in 7082 adults ≥65 years old, *Fluad* elicited significantly greater antibody responses than a nonadjuvanted, standard-dose inactivated vaccine.[26] In observational studies and randomized trials, older adults who received an adjuvanted inactivated vaccine were less likely to develop symptomatic influenza illness or be hospitalized for influenza or pneumonia than those who received a nonadjuvanted, standard-dose inactivated vaccine.[27-29]

Recombinant Vaccine – *Flublok*, a recombinant influenza vaccine produced without use of influenza virus or chicken eggs, contains 3 times the amount of antigen included in standard-dose inactivated influenza vaccines. It is FDA-licensed for use in persons ≥18 years old.

In a retrospective cohort study in 12.7 million adults ≥65 years old vaccinated during the 2019-2020 influenza season, the recombinant quadrivalent vaccine was more effective in preventing hospital visits than a nonadjuvanted, standard-dose inactivated quadrivalent vaccine, an adjuvanted trivalent vaccine, or a high-dose trivalent vaccine.[30]

Choice of Vaccine – In adults ≥65 years old, high-dose, adjuvanted, and recombinant influenza vaccines improved humoral and cell-mediated immune responses and reduced influenza-related medical encounters and hospitalization compared to standard-dose inactivated vaccines.[31,32] Few trials have directly compared the high-dose, adjuvanted, and recombinant vaccines in older adults and none have shown that any one is superior to another.

The ACIP recommends that adults ≥65 years old receive either a high-dose, adjuvanted, or recombinant influenza vaccine; if none of these vaccines are available, any age-appropriate influenza vaccine should be given.[1]

PREGNANCY — Vaccination protects pregnant women against influenza-associated illness, which can be especially severe during pregnancy, and protects their infants for up to 6 months after birth (influenza vaccines are not approved for use in infants <6 months old). Protection is greatest in infants born to mothers who were vaccinated during the third trimester.[33]

The ACIP and the American College of Obstetricians and Gynecologists (ACOG) recommend vaccinating pregnant women against influenza (see Timing section).[34,35] The live-attenuated intranasal vaccine *(FluMist)* should not be used during pregnancy.

Table 2. Seasonal Influenza Vaccines for 2024-2025

Vaccine[1]	Available Formulations[2]	Recommended Age[3]	Cost[4]
Standard-Dose Inactivated Trivalent (IIV3); egg-based			
Afluria (Seqirus)[5,6]	0.5 mL syringe	≥3 years	$20.90
	5 mL multidose vial[7]	≥6 months[8]	19.20
Fluarix (GSK)[9]	0.5 mL syringe	≥6 months	19.00
FluLaval (GSK)	0.5 mL syringe	≥6 months	19.00
Fluzone (Sanofi)	0.5 mL syringe, vial	≥6 months[10]	19.90
	5 mL multidose vial[7]	≥6 months[10]	18.50
High-Dose Inactivated Trivalent (HD-IIV3); egg-based			
Fluzone High-Dose (Sanofi)[11]	0.5 mL syringe	≥65 years[12]	72.60
Standard-Dose, Adjuvanted Inactivated Trivalent (aIIV3); egg-based			
Fluad (Seqirus)[13,14]	0.5 mL syringe	≥65 years[12]	72.60
Standard-Dose, Cell Culture-Based Inactivated Trivalent (ccIIV3)			
Flucelvax (Seqirus)[15]	0.5 mL syringe	≥6 months	31.70
	5 mL multidose vial[7]	≥6 months[16]	31.70
Recombinant Trivalent (RIV3)			
Flublok (Sanofi)[17]	0.5 mL syringe	≥18 years	72.60
Live-Attenuated Trivalent (LAIV3); egg-based			
FluMist (AstraZeneca)[9]	0.2 mL intranasal sprayer[18,19]	2-49 years[20]	Not available[21]

1. All inactivated trivalent vaccines and the recombinant vaccine are given by IM injection. The live-attenuated trivalent vaccine is given intranasally.
2. Single-dose vials and syringes are sold in boxes of 10. Multidose vials contain 10 doses.
3. Children 6 months to 8 years old who are being vaccinated for the first time, whose vaccination history is not known, or who have not received at least 2 lifetime doses of a trivalent or quadrivalent influenza vaccine before July 1, 2024 should receive 2 doses at least 4 weeks apart. The first dose should be given as soon as possible after the vaccine becomes available so that the second dose can be given by the end of October. Children in this age group who received ≥2 doses of a trivalent or quadrivalent influenza vaccine at any time before July 1, 2024 require only 1 dose.
4. Approximate WAC per dose. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. August 5, 2024. Reprinted with permission by First Databank, Inc. All rights reserved. ©2024. www.fdbhealth.com/policies/drug-pricing-policy.
5. May contain residual amounts of neomycin sulfate, polymyxin B, and hydrocortisone.
6. Delivery of *Afluria* via the *PharmaJet Stratis* needle-free injection system is FDA-licensed for persons 18-64 years old.
7. Contains ~25 mcg/0.5 mL dose of mercury; strong evidence shows no adverse outcomes related to exposure to vaccines containing mercury.
8. The dose is 0.25 mL for children 6-35 months old and 0.5 mL for those ≥3 years old.
9. May contain residual amounts of gentamicin sulfate.
10. The dose is either 0.25 mL or 0.5 mL for children 6-35 months old and 0.5 mL for those ≥3 years old. The 0.25-mL prefilled syringes are no longer available; if a prefilled syringe is used in children 6-35 months old, the dose volume should be 0.5 mL.
11. Contains 60 mcg of hemagglutinin antigen from each strain, compared to 15 mcg in standard-dose inactivated vaccines.
12. The ACIP recommends these vaccines as options for solid organ transplant recipients 18-64 years old who are receiving immunosuppressive therapy.
13. Contains MF59, an oil-in-water emulsion of squalene oil.
14. May contain residual amounts of neomycin, kanamycin, and hydrocortisone.
15. Uses mammalian cells for replication rather than hen eggs.
16. The dose is 0.5 mL for children ≥6 months old.
17. Contains 45 mcg of hemagglutinin antigen from each strain, compared to 15 mcg in standard-dose inactivated vaccines. Contains no egg protein.
18. Each 0.2-mL dose contains $10^{6.5}$-$10^{7.5}$ FFU (fluorescent focus units) of live-attenuated influenza virus reassortants from each strain.
19. Each single-use sprayer delivers one 0.2-mL intranasal dose (given as 0.1 mL in each nostril). If nasal congestion that could impair vaccine delivery to the nasal mucosa is present, an injectable vaccine should be used instead. If use of an injectable vaccine is unacceptable, influenza vaccination should be delayed.
20. Per ACIP, the live-attenuated intranasal vaccine is contraindicated for use in patients with a severe allergic reaction to any component of the vaccine or to a previous dose of any influenza vaccine, pregnant women, persons who are immunocompromised, persons with active communication between the CSF and oropharynx, nasopharynx, nose, or ear or any other cranial CSF leak, persons with cochlear implants, children 2-4 years old who have asthma or have had a wheezing episode within the previous 12 months, persons without a functioning spleen, children or adolescents taking aspirin or salicylate-containing therapy, close contacts of severely immunocompromised persons who require a protected environment, or patients treated with oseltamivir or zanamivir within the previous 48 hours, peramivir within the previous 5 days, or baloxavir marboxil within the previous 17 days. Use of influenza antiviral drugs <2 weeks after administration of the intranasal live-attenuated vaccine could inhibit replication of the vaccine virus, reducing the vaccine's effectiveness. Some medical conditions (e.g., renal impairment) may require a longer interval between the antiviral drug regimen and administration of *FluMist*. Patients of any age with asthma may be at increased risk of wheezing after administration of *FluMist*.
21. *FluMist* is expected to be available this season.

Most studies have not found an association between influenza vaccination and adverse pregnancy outcomes, but data demonstrating the safety of vaccination during the first trimester are limited.[36] In one prospective study of women who were pregnant or planning on becoming pregnant, exposure to an influenza vaccine before or during pregnancy was not associated with an increased rate of miscarriage.[37]

EGG ALLERGY — The recombinant vaccine *(Flublok)* and the cell culture-based inactivated vaccine *(Flucelvax)* do not contain egg protein. Other available influenza vaccines may contain trace amounts of egg protein (ovalbumin), but numerous studies have found that persons with a history of egg allergy are not at increased risk for an adverse reaction to influenza vaccines that are propagated in eggs.[38]

The ACIP, American Academy of Pediatrics (AAP), and Joint Task Force on Practice Parameters of the American Academy of Allergy Asthma and Immunology and the American College of Allergy Asthma and Immunology state that persons with a

history of egg allergy of any severity can receive any age-appropriate influenza vaccine without the need for additional safety measures.[1,2,39] The AAP adds that it is not necessary to inquire about egg allergy before administration of any influenza vaccine.[2]

IMMUNOCOMPROMISED PERSONS — The live-attenuated intranasal influenza vaccine *(FluMist)* should not be used in immunocompromised persons. Inactivated and recombinant vaccines are generally considered safe for use in such persons, but the immune response may be reduced. In two randomized trials in solid-organ transplant recipients, the high-dose vaccine induced significantly greater immune responses than standard-dose vaccines.[40,41] The ACIP states that the high-dose inactivated and adjuvanted inactivated influenza vaccines are acceptable options for solid organ transplant recipients 18-64 years old who are receiving immunosuppressive therapy. Separating the time of influenza vaccination from that of an immunocompromising intervention could be considered.

USE WITH OTHER VACCINES — Any influenza vaccine can be given at the same time as a **COVID-19 vaccine**, but the vaccines should be administered in separate arms. The ACIP states that coadministration of a **respiratory syncytial virus (RSV)** vaccine with other adult vaccines during the same visit is acceptable; RSV and influenza antibody titer levels are somewhat lower with coadministration than with sequential administration (~1 month apart).[42]

Inactivated and **recombinant** influenza vaccines can be administered concomitantly or sequentially with live, inactivated, or recombinant vaccines. The **live-attenuated** intranasal influenza vaccine can be given simultaneously with inactivated or other live vaccines; other live vaccines not administered simultaneously should be given at least 4 weeks later. Because of limited safety data on concurrent use of 2 or more **adjuvanted** vaccines, use of a nonadjuvanted influenza vaccine may be considered when another adjuvanted vaccine (e.g., *Shingrix*, *Heplisav-B*) is administered concurrently.

USE WITH INFLUENZA ANTIVIRALS — Any inactivated or recombinant influenza vaccine can be administered to persons receiving antiviral drugs for treatment or chemoprophylaxis of influenza. Use of oseltamivir (*Tamiflu*, and generics) or zanamivir *(Relenza)* within 48 hours before, peramivir *(Rapivab)* within 5 days before, or baloxavir marboxil *(Xofluza)* within 17 days before administration of the live-attenuated intranasal influenza vaccine could inhibit replication of the vaccine virus, reducing its effectiveness. Persons who receive any of these antiviral drugs during these specified times and through 2 weeks after administration of the live-attenuated vaccine should be revaccinated with an inactivated or recombinant influenza vaccine.

ADVERSE EFFECTS — Influenza vaccination has been associated with Guillain-Barré syndrome, but the absolute risk is very low (about 1-2 additional cases per million persons vaccinated) and influenza infection itself has been associated with the syndrome (about 17 cases per million patients hospitalized with influenza).[43] In a prospective cohort study in patients with diabetes, influenza vaccination was associated with hyperglycemia, but serum glucose levels returned to baseline 2 days after vaccination.[44]

Except for soreness at the injection site, adverse reactions to **inactivated** influenza vaccines are uncommon. In clinical trials, the **high-dose** vaccine *(Fluzone High-Dose)* caused more injection-site reactions than standard-dose influenza vaccines. Pain and tenderness at the injection site also occurred more frequently with an **adjuvanted** vaccine *(Fluad)* than with a nonadjuvanted vaccine. Delivery of *Afluria* by needle-free jet injector has resulted in more mild to moderate local reactions than delivery by standard needle and syringe.

The most common adverse reactions associated with the **live-attenuated** intranasal vaccine are runny nose, nasal congestion, fever, and sore throat. The vaccine may increase the risk of wheezing, especially in children <5 years old with recurrent wheezing and in persons of any age with asthma. Persons who receive the live-attenuated vaccine may shed the vaccine-strain virus for a few days after vaccination, but person-to-person transmission has been rare, and serious illness resulting from transmission has not been reported. Nevertheless, the ACIP recommends that persons who care for severely immunocompromised patients in protected environments should not receive the live-attenuated vaccine or should avoid contact with such patients for 7 days after receiving it. ■

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