

The Medical Letter[®]

on Drugs and Therapeutics

Volume 64

October 3, 2022

ISSUE No.
1660

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The Medical Letter®

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Volume 64 (Issue 1660)

October 3, 2022

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▶ Influenza Vaccine for 2022-2023

Annual vaccination in the US against influenza A and B viruses is recommended for everyone ≥ 6 months old without a contraindication.¹ Influenza vaccines that are available in the US for the 2022-2023 season are listed in Table 2.

COMPOSITION – All influenza vaccines available in the US this season are quadrivalent; they contain two influenza A and two influenza B virus antigens (see Table 1). Influenza A viruses are the main cause of influenza-related morbidity and mortality, especially in older adults. Influenza B illness is usually more severe in children, especially those < 5 years old.²

Table 1. 2022-2023 Influenza Vaccine Composition¹

Egg-Based Vaccines

A/Victoria/2570/2019 (H1N1)pdm09-like
A/Darwin/9/2021 (H3N2)-like
B/Austria/1359417/2021 (Victoria lineage)-like
B/Phuket/3073/2013 (Yamagata lineage)-like

Cell Culture-Based and Recombinant Vaccines

A/Wisconsin/588/2019 (H1N1)pdm09-like
A/Darwin/6/2021 (H3N2)-like
B/Austria/1359417/2021 (Victoria lineage)-like
B/Phuket/3073/2013 (Yamagata lineage)-like

1. All influenza vaccines available in the US for the 2022-2023 influenza season are quadrivalent.

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. Early vaccination (i.e., in July or August) may result in suboptimal immunity before the end of the influenza season, especially in older adults.³

The ACIP specifically recommends that pregnant women who are in the first or second trimester during July or August wait until September or October to be vaccinated, unless vaccination later is not possible; vaccination during July or August can be considered for women who are in their third trimester.¹

Key Points: Influenza Vaccine for 2022-2023

- ▶ Annual vaccination in the US against influenza A and B viruses is recommended for everyone ≥ 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 quadrivalent; they contain two influenza A and two influenza B virus antigens.
- ▶ Influenza vaccination reduces the incidence of laboratory-confirmed influenza and the risk of serious complications and death associated with influenza illness.
- ▶ In adults ≥ 65 years old, use of a high-dose, adjuvanted, or recombinant vaccine can improve immune responses and is preferentially recommended over other influenza vaccines.
- ▶ Pregnant women in any trimester should be vaccinated against influenza.
- ▶ The ACIP states that persons with a history of egg allergy can receive any age-appropriate influenza vaccine, but those with a history of severe egg allergy who receive an egg-based vaccine should be vaccinated in a medical setting supervised by a healthcare provider experienced in managing severe allergic reactions.

Children who require 2 doses (see Table 2, footnote 2) should receive the first dose as early as possible so that the second dose can be given by the end of October.

For persons with laboratory-confirmed COVID-19, vaccination should be postponed until the isolation period has ended.⁴

EFFECTIVENESS – Influenza vaccination reduces the incidence of laboratory-confirmed influenza and the risk of serious complications and death associated with influenza illness.⁵⁻⁸ 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 still can substantially reduce the risk of influenza-related hospitalization and death.^{9,10}

OLDER ADULTS – Older adults are at increased risk for severe influenza-associated illness, hospitalization, and death. They may have weaker immunogenic responses to influenza vaccination than younger persons, and their antibody levels may decline more rapidly, decreasing vaccine effectiveness.¹¹

In a cohort study of hospitalized adults ≥ 60 years old with cardiovascular disease, influenza vaccination was associated with a reduced risk of in-hospital mortality. It was also associated with a lower risk of recurrent hospitalization and respiratory disease in patients with ischemic heart disease.¹²

High-Dose Vaccine – *Fluzone High-Dose Quadrivalent*, 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 31,989 adults ≥ 65 years old during 2 influenza seasons, a high-dose inactivated trivalent vaccine (*Fluzone High-Dose*; no longer available) induced significantly greater antibody responses than a standard-dose inactivated trivalent vaccine and was 24% more effective in preventing laboratory-confirmed influenza illness.¹³ In several studies in adults ≥ 65 years old, use of a high-dose inactivated trivalent vaccine was associated with a reduced risk of respiratory-related and all-cause hospitalization and death compared to standard-dose inactivated trivalent vaccines.¹⁴⁻¹⁷

In a randomized trial in 5260 patients with high-risk cardiovascular disease, use of a high-dose inactivated trivalent vaccine over 3 influenza seasons did not significantly reduce all-cause mortality or cardiopulmonary hospitalizations compared to standard-dose inactivated quadrivalent vaccines.¹⁸

Adjuvanted Vaccine – *Fluad Quadrivalent*, 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, an adjuvanted inactivated trivalent vaccine (*Fluad*; no longer available) elicited significantly greater antibody responses against all three influenza strains than a nonadjuvanted inactivated trivalent vaccine.¹⁹ In several trials, older adults who received

an adjuvanted inactivated trivalent vaccine were less likely to develop symptomatic influenza illness or to be hospitalized for influenza or pneumonia than those who received a nonadjuvanted inactivated trivalent vaccine.²⁰⁻²²

Recombinant Vaccine – *Flublok Quadrivalent*, a recombinant influenza vaccine produced without the 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 randomized, double-blind trial in 8604 adults ≥ 50 years old during the A/H3N2-predominant 2014-2015 influenza season, the recombinant quadrivalent vaccine was 30% more effective than a nonadjuvanted standard-dose inactivated quadrivalent vaccine in preventing laboratory-confirmed influenza illness.²³

Choice of Vaccine – In a recent trial in community-dwelling adults 65-82 years old, high-dose, adjuvanted, and recombinant influenza vaccines improved humoral and cell-mediated immune responses compared to standard-dose inactivated vaccines.²⁴ Few trials have directly compared the high-dose, adjuvanted, and recombinant vaccines in older adults and none have shown that any one vaccine is superior to another.

For the first time, the Advisory Committee on Immunization Practices (ACIP) is recommending use of a high-dose, adjuvanted, or recombinant influenza vaccine over other available age-appropriate influenza vaccines in adults ≥ 65 years old; if one of these vaccines is not available, vaccination should not be delayed and a standard-dose, nonadjuvanted 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).²⁵ The ACIP and the American College of Obstetricians and Gynecologists (ACOG) recommend that pregnant women be vaccinated against influenza without regard to the trimester of pregnancy (see Timing section on page 153).^{26,27} Pregnant women can receive any age-appropriate inactivated or recombinant influenza vaccine; the intranasal live-attenuated vaccine (*FluMist Quadrivalent*) should not be used during pregnancy.

Table 2. Seasonal Influenza Vaccines for 2022-2023

Vaccine	Available Formulations ¹	Recommended Age ²	Cost ³
Standard-Dose Inactivated Quadrivalent (IIV4); egg-based			
<i>Afluria Quadrivalent</i> (Seqirus) ^{4,5}	0.5 mL syringe	≥3 years	\$19.30
	5 mL multidose vial ⁶	≥6 months ⁷	17.80
<i>Fluarix Quadrivalent</i> (GSK) ⁸	0.5 mL syringe	≥6 months	18.30
<i>FluLaval Quadrivalent</i> (GSK)	0.5 mL syringe	≥6 months	18.30
<i>Fluzone Quadrivalent</i> (Sanofi)	0.5 mL syringe, vial	≥6 months ⁹	18.60
	5 mL multidose vial ⁶	≥6 months ⁹	17.30
High-Dose Inactivated Quadrivalent (HD-IIV4); egg-based			
<i>Fluzone High-Dose Quadrivalent</i> (Sanofi) ¹⁰	0.7 mL syringe	≥65 years	60.70
Standard-Dose, Adjuvanted Inactivated Quadrivalent (aIIV4); egg-based			
<i>Fluad Quadrivalent</i> (Seqirus) ^{11,12}	0.5 mL syringe	≥65 years	62.30
Standard-Dose, Cell Culture-Based Inactivated Quadrivalent (ccIIV4)			
<i>Flucelvax Quadrivalent</i> (Seqirus) ¹³	0.5 mL syringe	≥6 months	27.70
	5 mL multidose vial ⁶	≥6 months ¹⁴	26.20
Recombinant Quadrivalent (RIV4)			
<i>Flublok Quadrivalent</i> (Sanofi) ¹⁵	0.5 mL syringe	≥18 years	60.70
Live-Attenuated Quadrivalent (LAIV4); egg-based			
<i>FluMist Quadrivalent</i> (AstraZeneca) ⁸	0.2 mL intranasal sprayer ^{16,17}	2-49 years ¹⁸	23.00

1. Single-dose vials and syringes are sold in boxes of 10. Multidose vials contain 10 doses.
2. 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, 2022 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, 2022 require only 1 dose.
3. 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, 2022. Reprinted with permission by First Databank, Inc. All rights reserved. ©2022. www.fdbhealth.com/policies/drug-pricing-policy.
4. May contain residual amounts of neomycin sulfate, polymyxin B, and hydrocortisone.
5. Delivery of *Afluria Quadrivalent* via the *PharmaJet Stratis* needle-free injection system is FDA-licensed for persons 18-64 years old.
6. Contains ~25 mcg/0.5 mL dose of mercury; strong evidence shows no increased risk from exposure to vaccines containing mercury.
7. The dose is 0.25 mL for children 6-35 months old and 0.5 mL for those ≥3 years old.
8. May contain residual amounts of gentamicin sulfate.
9. 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.
10. Contains 60 mcg of hemagglutinin antigen from each strain, compared to 15 mcg in standard-dose inactivated vaccines.
11. Contains MF59, an oil-in-water emulsion of squalene oil.
12. May contain residual amounts of neomycin, kanamycin, and hydrocortisone.
13. Uses mammalian cells for replication rather than hen's eggs.
14. The dose is 0.5 mL for children ≥6 months old.
15. Contains 45 mcg of hemagglutinin antigen from each strain, compared to 15 mcg in standard-dose inactivated vaccines. Contains no egg proteins.
16. 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.
17. 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 selected instead. If use of an injectable vaccine is unacceptable, influenza vaccination should be delayed.
18. Per ACIP, contraindicated for use in 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 spleen or with a nonfunctioning 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 efficacy. Some medical conditions (e.g., renal impairment) may require a longer interval between the antiviral drug regimen and administration of *FluMist Quadrivalent*. Patients of any age with asthma may be at increased risk of wheezing after administration of *FluMist Quadrivalent*.

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.²⁸

EGG ALLERGY – The recombinant vaccine (*Flublok Quadrivalent*) and the cell culture-based inactivated vaccine (*Flucelvax Quadrivalent*) do not contain egg protein. Other available influenza vaccines may contain trace amounts of egg protein (ovalbumin), but numerous studies have found that patients with a history of egg allergy are not at increased risk for a reaction to influenza vaccines that are propagated in eggs.²⁹

The ACIP states that persons with a history of egg allergy of any severity can receive any age-appropriate influenza vaccine, but those with a history of more severe egg allergy (angioedema, respiratory distress, light headedness, recurrent vomiting, or requiring epinephrine or another emergency medical intervention) who receive an egg-based vaccine should be vaccinated in a medical setting (e.g., doctor's office or clinic) supervised by a healthcare provider experienced in managing severe allergic reactions.¹

The 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 no special precautions are necessary for patients with egg allergy of any severity.³⁰ The American Academy of Pediatrics adds that it is not necessary to inquire about egg allergy before administration of any influenza vaccine, including on screening forms.³¹

IMMUNOCOMPROMISED PERSONS — The live-attenuated influenza vaccine 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.^{32,33} Separating the time of influenza vaccination from that of an immunocompromising intervention might 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 at different sites. **Inactivated** and **recombinant** influenza vaccines can be administered concomitantly or sequentially with live or other inactivated or recombinant vaccines. The **live-attenuated** 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. Use of a nonadjuvanted influenza vaccine could be considered in persons receiving an **adjuvanted** non-influenza vaccine (e.g., *Shingrix*, *Heplisav-B*); coadministration of *Shingrix* and a nonadjuvanted inactivated quadrivalent influenza vaccine has not been associated with a decrease in the immunogenicity of either vaccine or safety concerns.³⁴

USE WITH INFLUENZA ANTIVIRALS — 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 intranasal live-attenuated influenza vaccine could inhibit replication of the vaccine virus, reducing the vaccine's efficacy. Persons who receive any of these antiviral drugs during these specified times and through 2 weeks after receiving 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 one million patients hospitalized with influenza).³⁵ In a prospective cohort study in patients with diabetes, influenza vaccination was associated with hyperglycemia, but serum glucose levels returned to baseline 2 days post-vaccination.³⁶

Except for soreness at the injection site, adverse reactions to **inactivated** influenza vaccines are uncommon. In clinical trials, the trivalent formulation of *Fluzone High-Dose* (no longer available) caused more injection-site reactions than standard-dose influenza vaccines. Pain and tenderness at the injection site also occurred more frequently with *Fluad* (adjuvanted trivalent) 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** 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. A recent study, however, in 151 children with asthma found that the risk of asthma exacerbations was similar with the live-attenuated influenza vaccine and a quadrivalent inactivated influenza vaccine.³⁷ 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 states 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.

INVESTIGATIONAL VACCINES — Vaccines that provide universal protection against all influenza strains are in development. A vaccine designed to protect against influenza, COVID-19, and respiratory syncytial virus, the three primary causes of viral respiratory disease in older adults, and a vaccine against both influenza and COVID-19 are also in development. ■

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