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To: Physicians, Pharmacists, Infection Preventionists, Long-Term Care Facilities, Local Health Departments, Tribal Health Clinics, Federally Qualified Health Centers, Visiting Nurse Agencies, and other immunization providers

From: James H. Conway, MD, FAAP

Wisconsin Chapter of the American Academy of Pediatrics

Jonathan L. Temte, MD, PhD

Chair, Wisconsin Council on Immunization Practices

Sheryl Bedno, MD, DrPH, FACOEM

Chief Medical Officer and State Epidemiologist for Environmental and Occupational Health

Re: The 2024–2025 Advisory Committee on Immunization Practices (ACIP) recommendations for the prevention and control of seasonal influenza, respiratory syncytial virus (RSV), and COVID-19 with vaccines

Promote Influenza, Respiratory Syncytial Virus (RSV), and COVID-19 Vaccination

Influenza, RSV, and SARS-CoV-2 viruses are expected to circulate at the same time during the upcoming 2024–2025 respiratory virus season. In this context, vaccination will be important to decrease the overall impact of respiratory illnesses by reducing respiratory virus-associated illnesses, hospitalizations, and deaths, and reducing the burden on the health care system.

Health care providers should promote and offer:

- Influenza vaccine among *all* persons aged 6 months and older annually starting during September or October.
- RSV vaccine year-round among older adults and September through January among pregnant persons.
- Monoclonal antibody for the prevention of RSV among newborn infants and young children during October through March.
- COVID vaccine among *all* persons aged 6 months and older when vaccine becomes available.

Seasonal influenza vaccine should be offered as long as influenza viruses are circulating. <u>Influenza was detected in Wisconsin residents during all 52 weeks of 2023</u> (the most current year for which we have complete data). Immunization clinics should therefore be scheduled throughout the respiratory virus season into 2025.

Updated ACIP Recommendations

The 2024–2025 ACIP recommendations for the prevention and control of seasonal influenza with vaccines were formally issued on August 29, 2024. This document can be downloaded from the MMWR website.

Updated ACIP information regarding <u>recommendations</u> or <u>vaccine supply and timing of distribution</u> of influenza, RSV, or COVID-19 vaccines that affect the target groups will be made available, as needed. The 2024–2025 <u>Vaccine Information Statements</u> are also available.

It is important to be aware of the current recommendations and to periodically visit the CDC website for additional information and updates. Access to updated or supplemental information is often necessary throughout the respiratory virus season. The CDC and other public health agencies will assess the vaccine supply on a continuing basis throughout the manufacturing period and will inform both providers and the general public in the event of substantial delays or inadequate supply.

Influenza vaccines available during the 2024–2025 season are (Table 1):

- Trivalent inactivated influenza vaccine (IIV3).
 - o Sanofi Pasteur (Fluzone Trivalent)
 - o GlaxoSmithKline (Fluarix Trivalent)
 - o GlaxoSmithKline (FluLaval Trivalent)
 - o Seqirus (Afluria Trivalent)
 - o Sanofi Pasteur (Fluzone High-Dose Trivalent)
- Trivalent cell-culture based influenza vaccine (ccIIV3): Seqirus (Flucelvax Trivalent).
- Live-attenuated influenza vaccine, trivalent (LAIV3): AstraZeneca (FluMist Trivalent).
- Adjuvanted inactivated influenza vaccine, trivalent (aIIV3): Sequirus (Fluad Trivalent).
- Recombinant hemagglutinin (HA) influenza vaccine (RIV3): Sanofi Pasteur (FluBlok Trivalent).

Vaccination of all persons aged ≥6 months is recommended. Not all influenza vaccines are uniformly available in any given practice setting or geographic locality. ACIP recommends that adults aged ≥65 years preferentially receive an enhanced influenza vaccine (EIV) to improve their immunity. Any one of the following enhanced vaccines are preferred for this group: trivalent high-dose inactivated influenza vaccine (HD-IIV3), RIV3, or aIIV3. If none of these three vaccines are available at an opportunity for vaccine administration, then any other age-appropriate influenza vaccine can be used. Vaccination should not be delayed to obtain a specific product when an appropriate one is already available. To avoid missed opportunities for vaccination, providers should offer vaccination during routine health care visits and hospitalizations when vaccine is available. See Table 2 for a list of contraindications and precautions to receipt of influenza vaccine.

We are not aware of any supply issues. In the event of a shortfall in production or a delay in the delivery of an adequate supply of vaccine, you will be notified of any official prioritization of high-risk groups. If such an event should occur, a Prioritization Plan will be distributed. If needed, this plan will provide a sequence of prioritization for you to follow to assure that high-risk individuals receive their influenza vaccinations first. Because the annual supply and timing of distribution of influenza vaccine cannot be guaranteed, we continue to stress the importance of local partnerships. The recent history of vaccine delivery delays and shortages emphasizes the need for local coalitions to help coordinate redistribution and administration of influenza vaccine. Vaccines.gov may be used to identify a location (for example, clinic or community pharmacy) to receive influenza vaccine.

The 2024–2025 ACIP Recommendations include two principal updates:

• The composition of the 2024–2025 U.S. seasonal influenza vaccines includes updates to the influenza A(H3N2) component. Also, for the 2024–25 influenza season, FDA has recommended that the U.S. seasonal influenza vaccine composition no longer include influenza B/Yamagata, as there have been no confirmed detections of influenza B/Yamagata viruses in global influenza surveillance since March 2020.

Trivalent egg-based vaccine will contain: A/Victoria/4897/2022 (H1N1)pdm09-like virus. A/Thailand/8/2022 (H3N2)-like virus (updated). B/Austria/1359417/2021 (Victoria lineage)-like virus.

Cell culture-based or recombinant vaccine will contain: A/Wisconsin/67/2022 (H1N1)pdm09-like virus. A/Massachusetts/18/2022 (H3N2)-like virus (updated). B/Austria/1359417/2021 (Victoria lineage)-like virus.

 Recommendations for vaccination of adult solid organ transplant recipients have been updated to include HD-IIV3 and aIIV3 as acceptable options for solid organ transplant recipients aged 18 through 64 years who are receiving immunosuppressive medication regimens (without a preference over other ageappropriate IIV3s or RIV3).

Influenza vaccination of children aged 6 months through 8 years

All children aged 6 months through 8 years who are recommended to receive two doses this season should receive their first dose as soon as possible after vaccine becomes available; these children should receive the second dose \geq 4 weeks later (Figure 1). This practice increases the opportunity for both doses to be administered during the same influenza season and before the onset of influenza activity.

Influenza vaccination of pregnant women

- Vaccination during pregnancy has been demonstrated to protect infants from influenza, including infants aged <6 months for whom no influenza vaccines are currently licensed. Specifically, infants born to vaccinated women had a 63% reduction in laboratory-confirmed influenza illness during the first six months of life (2,3).
- The ACIP, the American College of Obstetricians and Gynecologists (ACOG), and the American Academy of Family Physicians (AAFP) recommend that all women who are pregnant or who might be pregnant during the upcoming influenza season receive IIV because of an increased risk of serious illness and complications from influenza. LAIV is not recommended for use during pregnancy.
- Information about influenza vaccination during pregnancy and guidance on <u>how to address concerns</u> that patients may have about influenza vaccination is available.

Influenza vaccination of persons with a history of egg allergy

For the 2024–2025 influenza season, ACIP recommends the following:

- ACIP recommends that all persons aged ≥6 months with egg allergy should receive influenza vaccine. Any influenza vaccine (egg based or nonegg based) that is otherwise appropriate for the recipient's age and health status can be used.
- It is no longer recommended that persons who have had an allergic reaction to egg involving symptoms other than urticaria should be vaccinated in an inpatient or outpatient medical setting supervised by a health care provider who is able to recognize and manage severe allergic reactions if an egg-based vaccine is used. 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. All vaccines should be administered in settings in which personnel and equipment needed for rapid recognition and treatment of acute hypersensitivity reactions are available.

RSV Vaccine Recommendation

For older adults:

- A single dose of RSV vaccine is recommended for all adults aged ≥75 years and for adults aged 60–74 years who are <u>at increased risk for severe RSV disease</u>. If a patient received a dose of RSV vaccine during the previous respiratory virus season an additional dose is not indicated.
- Adults aged 60–74 years who are at increased risk include persons with certain chronic medical conditions, persons with moderate or severe immune compromise, and persons living in nursing homes.
- Adults aged ≥60 years may receive any RSV vaccine licensed for adults aged ≥60 years (Arexvy [GSK], Abrysvo [Pfizer], or mResvia [Moderna]).

For pregnant persons:

• A single dose of Abrysvo should be administered to pregnant persons during September–January during weeks 32–36 of pregnancy (32 weeks 0 days through 36 weeks 6 days) to target vaccine among pregnant persons whose infants will be in their first months of life, when protection from maternal vaccination would be at its highest, during the RSV season.

See also ACIP guidance for administration of monoclonal antibody for the prevention of RSV among infants and young children.

COVID-19 Vaccine Recommendation

- Persons aged 5 years and above who are not immunocompromised are recommended to receive a single dose of COVID-19 vaccine (2024–2025 Formula) regardless of receipt of previous COVID-19 vaccine.
- Recommendations for persons aged 6 months through 4 years and persons with immunocompromise are described on the <u>Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States</u> webpage.

Coadministration

Providers may simultaneously administer COVID-19, influenza, and RSV vaccines to eligible patients in order to avoid missed opportunities.

Abrysvo can be administered to pregnant persons with other recommended vaccines, such as tetanus, diphtheria, and pertussis (Tdap), influenza, and COVID-19 vaccines, without regard to timing, including simultaneous vaccination at different anatomic sites on the same day.

If you have questions, please contact your Regional Immunization Program Representative:

Shayna Nickell	Eau Claire Regional Office	608-692-3541
Susan Nelson	Green Bay Regional Office	920-448-5231
Stacey Moyer	Madison Central Office	608-266-9316
Monica Thakur	Milwaukee Regional Office	414-227-3995
Christie Larmie	Rhinelander Regional Office	715-365-2709

References

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- 2. Zaman K, Roy E, Arifeen SE, et al. Effectiveness of maternal influenza immunization in mothers and infants. N Engl J Med 2008;359:1555–64.
- 3. Tapia MD, Sow SO, Tamboura B, et al. Maternal immunisation with trivalent inactivated influenza vaccine for prevention of influenza in infants in Mali: a prospective, active-controlled, observer-blind, randomised phase 4 trial. Lancet Infect Dis. 2016;16(9):1026-1035.
- 4. Buchan SA, Booth S, Scott AN, et al. Effectiveness of live attenuated vs inactivated influenza vaccines in children during the 2012-2013 through 2015-206 influenza seasons in Alberta, Canada. JAMA Pediatr. 2018;172(9):e181514.doi:10.1001/jamapediatrics.2018.1514

TABLE 1. Influenza vaccines, by formulation—United States, 2024–2025 influenza season*

Trade name	Manufacturer	Presentation	Mercury (from thimerosal) (μg/0.5 mL)	Age indication	Route	HA (IIVs and RIV4) or virus count (LAIV4) for each vaccine virus (per dose)		
Inactivated influenza vaccine, trivalent (IIV3), standard dose, egg based [†]								
		0.5 mL PFS§	**	≥3 yrs [§]	IM [¶]	15 μg/0.5 mL		
Afluria	Seqirus	5.0 mL MDV [§]	24.5	≥6 mos [§] (needle syringe) 18-64 yrs (jet injector)	e/ IM¶	7.5 μg/0.25 mL 15 μg/0.5 mL		
Fluarix	GlaxoSmithKline	0.5 mL PFS		≥6 mos	IM [¶]	15 μg/0.5 mL		
FluLaval	GlaxoSmithKline	0.5 mL PFS		≥6 mos	IM¶	15 μg/0.5 mL		
Fluzone	Sanofi Pasteur	0.5 mL PFS ^{††}		≥6 mos ^{††}	IM [¶]	15 μg/0.5 mL		
		$5.0~\text{mL MDV}^{\dagger\dagger}$	25	≥6 mos ^{††}	IM [¶]	7.5 µg/0.25 mL		
						15 μg/0.5 mL		
Inactivated inf	Inactivated influenza vaccine, cell culture-based trivalent (ccIIV3), standard dose							
Flucelvax	Seqirus	0.5 mL PFS		≥6 mos	IM^\P	15 μg/0.5 mL		
		5.0 mL MDV	25	≥6 mos	IM [¶]	15 μg/0.5 mL		
Adjuvanted inactivated influenza vaccine, trivalent (aIIV3), standard dose, egg based [†]								
Fluad	Seqirus	0.5 mL PFS		≥65 yrs	IM¶	15 μg/0.5 mL		
Inactivated in	fluenza vaccine, tri	valent (HD-IIV3), h	igh dose, egg based	[†				
Fluzone High- Dose	Sanofi Pasteur	0.5 mL PFS		≥65 yrs	IM¶	60 μg/0.5 mL		
Recombinant	influenza vaccine, t	rivalent (RIV3)						
FluBlok	Sanofi Pasteur	0.5 mL PFS		≥18 yrs	IM^\P	45 μg/0.5 mL		
Live attenuate	d influenza vaccine	e, trivalent (LAIV3)	, egg based [†]					
FluMist	AstraZeneca	0.2 mL prefilled single-use intranasal sprayer		2–49 yrs	NAS	10 ^{6.5-7.5} fluorescent focus units/0.2 mL		

Abbreviations: ACIP = Advisory Committee on Immunization Practices; FDA = Food and Drug Administration; HA = hemagglutinin; IIV3 = inactivated influenza vaccine, trivalent; IM = intramuscular; LAIV3 = live attenuated influenza vaccine, trivalent; MDV = multidose vial; NAS = intranasal; PFS = prefilled syringe; RIV3 = recombinant influenza vaccine, trivalent.

^{*} Manufacturer package inserts and updated CDC and ACIP guidance should be consulted for additional information concerning, but not limited to, indications, contraindications, warnings, and precautions. Package inserts for U.S.-licensed vaccines are available at https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states. Availability and characteristics of specific products and presentations might change or differ from what is described in this table and in the text of this report.

[†] Although a history of severe allergic reaction (e.g., anaphylaxis) to egg is a labeled contraindication to the use of egg-based IIV3s and LAIV3, ACIP recommends that all persons aged ≥6 months with egg allergy should receive influenza vaccine and that any influenza vaccine (egg based or nonegg based) that is otherwise appropriate for the recipient's age and health status can be used (see Persons with a History of Egg Allergy).

TABLE 2. Contraindications and precautions to the use of influenza vaccines—United States, 2024–2025 influenza season*

Vaccine	Contraindications	Precautions
Egg-	History of severe allergic reaction (for example, anaphylaxis) to	Moderate or severe acute illness with or
based	any component of the vaccine [†] or to a previous dose of any	without fever
IIV3s	influenza vaccine (that is, any egg-based IIV, ccIIV, RIV, or	History of Guillain-Barré syndrome within
	LAIV)§	six weeks of receipt of influenza vaccine
ccIIV3	History of severe allergic reaction (for example, anaphylaxis) to	Moderate or severe acute illness with or
	a previous dose of any ccIIV or any component of ccIIV3§	without fever
		History of Guillain-Barré syndrome within
		six weeks of receipt of influenza vaccine
		History of severe allergic reaction to a
		previous dose of any other influenza vaccine
		(that is, any egg-based IIV, RIV, or LAIV)¶
RIV3	History of severe allergic reaction (for example, anaphylaxis) to	Moderate or severe acute illness with or
	a previous dose of any RIV or any component of RIV3§	without fever
		History of Guillain-Barré syndrome within
		six weeks of receipt of influenza vaccine
		History of severe allergic reaction to a
		previous dose of any other influenza vaccine
		(that is, any egg-based IIV, ccIIV, or
		LAIV)¶
LAIV	History of severe allergic reaction (for example, anaphylaxis) to	Moderate or severe acute illness with or
	any component of the vaccine [†] or to a previous dose of any	without fever
	influenza vaccine (that is, any egg-based IIV, ccIIV, RIV, or	History of Guillain-Barré syndrome within
	LAIV)§	six weeks of receipt of influenza vaccine
	Concomitant aspirin or salicylate-containing therapy in children	Asthma in persons aged ≥5 years
	and adolescents§	Other underlying medical conditions that
	Children aged 2 through 4 years who have received a diagnosis	might predispose to complications after
	of asthma or whose parents or caregivers report that a health	wild-type influenza infection (for example,
	care provider has told them during the preceding 12 months that	chronic pulmonary, cardiovascular [except
	their child had wheezing or asthma or whose medical record	isolated hypertension], renal, hepatic,
	indicates a wheezing episode has occurred during the preceding	neurologic, hematologic, or metabolic
	12 months	disorders [including diabetes mellitus])
	Children and adults who are immunocompromised due to any	
	cause, including but not limited to immunosuppression caused	
	by medications, congenital or acquired immunodeficiency	
	states, HIV infection, anatomic asplenia, or functional asplenia	
	(for example, due to sickle-cell anemia)	
	Close contacts and caregivers of severely immunosuppressed	
	persons who require a protected environment	

[§] The approved dose volume for Afluria Trivalent is 0.25 mL for children aged 6 through 35 months and 0.5 mL for persons aged ≥3 years. However, 0.25-mL prefilled syringes are no longer available. For children aged 6 through 35 months, a 0.25-mL dose must be obtained from a multidose vial.

[¶] IM-administered influenza vaccines should be given by needle and syringe only, with the exception of the MDV presentation of Afluria Trivalent, which may alternatively be given by the PharmaJet Stratis jet injector for persons aged 18 through 64 years only. For adults and older children, the recommended site for intramuscular influenza vaccination is the deltoid muscle. The preferred site for infants and young children is the anterolateral aspect of the thigh. Additional specific guidance regarding site selection and needle length for intramuscular administration is available in the ACIP General Best Practice Guidelines for Immunization.

^{**} Not applicable.

^{††} Fluzone is approved for ages 6 through 35 months at either 0.25 mL or 0.5 mL per dose; however, 0.25-mL prefilled syringes are no longer available. If a prefilled syringe of Fluzone is used for a child in this age group, the dose volume will be 0.5 mL per dose.

Pregnancy
Persons with active communication between the CSF and the oropharynx, nasopharynx, nose, or ear or any other cranial CSF leak

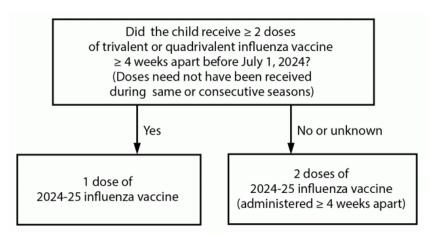
Persons with cochlear implants**

Receipt of influenza antiviral medication within the previous 48 hours for oseltamivir and zanamivir, previous 5 days for peramivir, and previous 17 days for baloxavir^{††}

Abbreviations: ACIP = Advisory Committee on Immunization Practices; ccIIV = cell culture—based inactivated influenza vaccine (any valency); ccIIV3 = cell culture—based inactivated influenza vaccine, trivalent; CSF = cerebrospinal fluid; FDA = Food and Drug Administration; IIV = inactivated influenza vaccine (any valency); IIV3 = inactivated influenza vaccine, trivalent; LAIV = live attenuated influenza vaccine (any valency); LAIV3 = live attenuated influenza vaccine, trivalent; RIV = recombinant influenza vaccine (any valency); RIV3 = recombinant influenza vaccine, trivalent.

- * Manufacturer package inserts and updated CDC and ACIP guidance should be consulted for additional information concerning, but not limited to, indications, contraindications, warnings, and precautions. When a contraindication is present, a vaccine should not be administered. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction (see the General Best Practice Guidelines for Immunization, available at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html). Package inserts for U.S.-licensed vaccines are available at https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states.
- [†] Although a history of severe allergic reaction (e.g., anaphylaxis) to egg is a labeled contraindication to the use of egg-based IIV3s and LAIV3, ACIP recommends that all persons aged ≥6 months with egg allergy should receive influenza vaccine, and that any influenza vaccine (egg based or nonegg based) that is otherwise appropriate for the recipient's age and health status can be used (see Persons with a History of Egg Allergy).
- § Labeled contraindication noted in package insert.
- ¶ If administered, vaccination should occur in a medical setting and should be supervised by a health care provider who can recognize and manage severe allergic reactions. Providers can consider consultation with an allergist in such cases, to assist in identification of the component responsible for the allergic reaction.
- ** Age-appropriate injectable vaccines are recommended for persons with cochlear implant due to the potential for CSF leak, which might exist for a period after implantation. Providers might consider consultation with a specialist concerning risk for persistent CSF leak if an age-appropriate inactivated or recombinant vaccine cannot be used.
- ^{††} Use of LAIV3 in context of influenza antivirals has not been studied; however, interference with activity of LAIV3 is biologically plausible, and this possibility is noted in the package insert for LAIV3. In the absence of data supporting an adequate minimum interval between influenza antiviral use and LAIV3 administration, the intervals provided are based on the half-life of each antiviral. The interval between influenza antiviral receipt and LAIV3 for which interference might potentially occur might be further prolonged in the presence of medical conditions that delay medication clearance (for example, renal insufficiency). Influenza antivirals might also interfere with LAIV3 if initiated within two weeks after vaccination. Persons who receive antivirals during the period starting with the specified time before receipt of LAIV3 through two weeks after receipt of LAIV3 should be revaccinated with an age-appropriate IIV3 or RIV3.

Figure 1. Influenza vaccine dosing algorithm for children aged 6 months through 8 years* — Advisory Committee on Immunization Practices, United States, 2024–25 influenza season.



^{*} Children aged 6 months through 8 years who require 2 doses of influenza vaccine should receive their first dose as soon as possible (including during July and August, if vaccine is available) to allow the second dose (which must be administered ≥4 weeks later) to be received, ideally, by the end of October. For children aged 8 years who require 2 doses of vaccine, both doses should be administered even if the child turns age 9 years between receipt of dose 1 and dose 2.