Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP)—United States, 2017-18 Summary of Recommendations

For additional information: *MMWR Recomm Rep 2017;66(RR-2)*:1-20 (<u>https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html</u>) Note: The contents of this document are available in HTML format at <u>https://www.cdc.gov/flu/professionals/acip/2017-18summary.htm</u>.

GROUPS RECOMMENDED FOR VACCINATION

- Routine annual influenza vaccination is recommended for all persons aged ≥6 months who do not have contraindications.
 - Emphasis should be placed on vaccination of high-risk groups and their contacts and caregivers (no hierarchy is implied by order of listing):
 - Children aged 6-59 months;
 - Adults aged \geq 50 years;
 - Persons with chronic pulmonary (including asthma), cardiovascular (except isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus);
 - Persons who are immunocompromised due to any cause, (including medications or HIV infection);
 - Women who are or will be pregnant during the influenza season;
 - Children and adolescents (aged 6 months through 18 years) receiving aspirin- or salicylate-containing medications and who might be at risk for Reye syndrome;
 - Residents of nursing homes and other long-term care facilities;
 - o American Indians/Alaska Natives;
 - Persons who are extremely obese (BMI \geq 40); and
 - Caregivers and contacts of those at risk:
 - Health care personnel in inpatient and outpatient care settings, medical emergency-response workers, employees of nursing home and long-term care facilities who have contact with patients or residents, and students in these professions who will have contact with patients;
 - Household contacts and caregivers of children aged ≤59 months (i.e., <5 years), particularly contacts of children aged <6 months, and adults aged ≥50 years; and
 - Household contacts and caregivers of persons who are in one of the high-risk categories listed above.

INFLUENZA VACCINE COMPOSITION FOR 2017-18

- All 2017-18 influenza vaccines licensed in the United States will contain hemagglutinin (HA) derived from influenza viruses antigenically similar to those recommended by FDA.
- 2017–18 trivalent vaccines:
 - an A/Michigan/45/2015 (H1N1)pdm09–like virus;
 - o an A/Hong Kong/ 4801/2014 (H3N2)-like virus; and
 - a B/Brisbane/60/2008-like virus (Victoria lineage).
- 2017–18 quadrivalent vaccines:
 - the same three HA antigens as trivalent vaccines, plus
 - o a B/Phuket/3073/2013-like virus (Yamagata lineage).

TIMING OF VACCINATION

- Optimally, vaccination should occur before onset of influenza activity in the community.
 - Vaccination should be offered by end of October, if possible.
 - Vaccination should be offered as long as influenza viruses are circulating and unexpired vaccine is available.
- Children aged 6 months through 8 years who require 2 doses should receive their first dose as soon as possible after vaccine becomes available, and the second dose ≥4 weeks later.

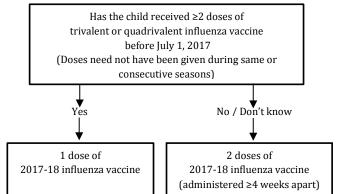
GUIDANCE FOR USE IN SPECIFIC SITUATIONS

Volume per Dose for Children and Adults

- Children aged 6 through 35 months may receive:
 - 0.5mL Fluarix Quadrivalent (IIV4) intramuscularly, or
 - 0.5mL FluLaval Quadrivalent (IIV4) intramuscularly, or
 0.25mL Fluzone Quadrivalent (IIV4) intramuscularly.
 - Note that dose volume differs for these three brands. Care should be taken to administer the correct dose.
- Children aged 3 through 17 years may receive 0.5mL intramuscularly of an age-appropriate IIV formulation.
- Adults aged 18 years and older may receive 0.5mL intramuscularly of an age-appropriate IIV or RIV.
 - Alternatively, adults aged 18 through 64 years may receive
 0.1mL intradermally of Fluzone Intradermal Quadrivalent (administered using the included delivery device).
- If a smaller intramuscular dose (e.g., 0.25mL) is administered to an adult, an additional dose should be administered to provide a full 0.5mL dose. If the error is discovered later (after the recipient has left the vaccination setting), a full 0.5mL dose should be administered as soon as the recipient can return.

Number of Doses for Children Aged 6 Months through 8 Years

• Determine the number of doses needed for this age group as follows:



Pregnant Women

- All women who are pregnant or who might be pregnant during the influenza season should receive influenza vaccine.
 - Any licensed, recommended, and age-appropriate influenza vaccine may be used.
 - **LAIV is not recommended for use in any population for 2017-18.** Providers who use it should note that LAIV should not be used during pregnancy.
- Influenza vaccine can be administered at any time during pregnancy, before and during the influenza season.

<u>Adults Aged ≥65 years</u>

- May receive any age-appropriate IIV (standard- or high-dose, trivalent or quadrivalent, adjuvanted or unadjuvanted) or RIV.
- High-dose IIV3 exhibited superior efficacy over comparator standard-dose IIV3 in a large randomized trial, and may provide better protection than standard dose IIV3 for this age group.
- However, vaccination should not be delayed to find a particular product if an appropriate one is available.

Immunocompromised Persons

- LAIV is not recommended for use in any population for 2017-18. Providers who use it should note that LAIV should not be used for immunocompromised persons.
- Immunocompromised persons should receive an age-appropriate
 IIV or RIV
- Immune response to vaccines might be blunted in immunocompromised persons.
- Timing of vaccination might be a consideration (e.g., in some period before or after an immunocompromising intervention).
- The Infectious Diseases Society of America (IDSA) has published detailed guidance for the selection and timing of vaccines for persons with specific immunocompromising conditions (https://academic.oup.com/cid/article/58/3/e44/336537)

High-Risk Persons and their Caregivers and Contacts

- High-risk persons and their caregivers and contacts (including those of immunosuppressed persons) may receive any ageappropriate IIV or RIV
- LAIV is not recommended for use in any population for 2017-18. Providers who use it should note that health care personnel or hospital visitors who receive LAIV should avoid providing care for severely immunosuppressed persons (those requiring a protected environment) for 7 days after vaccination.

Persons with a History of Egg Allergy

- Persons who are able to eat lightly cooked egg (e.g., scrambled egg) without reaction are unlikely to be egg-allergic.
- Persons who have experienced only hives after exposure to egg should receive any licensed, recommended, age-appropriate influenza vaccine (i.e., IIV or RIV).
- Persons reporting symptoms other than hives, such as angioedema, respiratory distress, lightheadedness, or recurrent emesis; or who required epinephrine or another emergency medical intervention, may also receive any licensed and recommended influenza vaccine that is otherwise appropriate.
 - Additionally, for these persons, vaccine should be administered in an inpatient or outpatient medical setting and supervised by a health care provider who is able to recognize and manage severe allergic conditions.
- A previous severe allergic reaction to influenza vaccine, regardless of the component suspected of causing the reaction, is a contraindication to future receipt of the vaccine.

Vaccination Issues for Travelers

- Travelers who wish to reduce the risk for influenza infection should consider influenza vaccination, preferably ≥2 weeks before departure.
- Persons at high risk for complications of influenza who were not vaccinated during the preceding fall or winter should consider receiving influenza vaccine before departure, if they plan to travel to the tropics, with organized tourist groups or on cruise ships, or to the Southern Hemisphere during April–September.
- Influenza vaccine formulated for the Southern Hemisphere might differ in viral composition from Northern Hemisphere vaccine.
- Southern Hemisphere influenza vaccines are generally not available in the U.S.

Vaccination and Influenza Antiviral Medications

- IIV and RIV may be administered to persons receiving influenza antiviral medications for treatment or chemoprophylaxis.
- LAIV is not recommended for use in any population for 2017-18. If used, note that influenza antivirals may reduce the effectiveness of LAIV, if administered within 48 hours before to 2 weeks after vaccination.

CONCURRENT ADMINISTRATION OF INFLUENZA VACCINE WITH OTHER VACCINES

- IIVs and RIV may be administered concurrently or sequentially with other inactivated or live vaccines.
- LAIV is not recommended for use in 2017–18. If used, note that LAIV may be administered simultaneously with another live vaccine. However, if given sequentially, at least 4 weeks should pass between administration of LAIV and another live vaccine.

STORAGE AND HANDLING OF INFLUENZA VACCINES

- Manufacturer packaging information should be consulted for authoritative guidance regarding storage and handling of all influenza vaccines.
- Vaccines should be protected from light and stored at recommended temperatures.
- Influenza vaccines are recommended to be stored refrigerated between 2° to 8°C (36° to 46°F).

• Vaccine that has been frozen should be discarded.

- Single-dose vials should not be accessed for more than one dose.
- Multiple-dose vials should be returned to recommended storage conditions between uses, and once initially accessed should not be kept beyond the recommended period of time.
- Vaccines should not be used after the expiration date on the label.

VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS)

- VAERS is the national vaccine safety monitoring system that is co-managed by CDC and FDA.
- VAERS serves as an early warning system to detect possible safety problems with U.S. vaccines.
- Health care providers are required to report any adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine, and adverse events listed in the table posted at:

https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_ Following_Vaccination.pdf.

• For information on how to report to VAERS go the VAERS website at https://vaers.hhs.gov/index.html.

FURTHER INFORMATION

CDC Influenza Information

- General influenza page: <u>www.cdc.gov/flu</u>.
- CDC FluView: <u>www.cdc.gov/flu/weekly</u>.
- Periodic influenza updates: <u>www.cdc.gov/mmwr</u>.
- Influenza Antiviral Guidance: <u>https://www.cdc.gov/flu/professionals/antivirals/index.htm</u>.
- For more information regarding influenza, call CDC at (800) 232-4636.

American Academy of Pediatrics (AAP) Guidance

• <u>http://redbook.solutions.aap.org/ss/influenza-resources.aspx</u>.

Infectious Diseases Society of America (ISDA) Guidance

https://academic.oup.com/cid/article/58/3/e44/336537

Manufacturer package inserts

 www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProdu cts/ucm093833.htm

U.S. INFLUENZA VACCINE PRODUCTS FOR THE 2017-18 SEASON

TRADE NAME [MANUFACTURER]	PRESENTATION	AGE INDICATION	MERCURY, μG/0.5ML	LATEX	ROUTE
IIV QUADRIVALENT, STANDARD-DOSE (SD-IIV4)				
Afluria Quadrivalent [Seqirus]	0.5 mL prefilled syringe	≥5 yrs	NR	No	IM
	5.0 mL multi-dose vial	≥5 yrs (needle/syringe) 18 through 64 yrs (jet injector)	24.5	No	IM
Fluarix Quadrivalent [GlaxoSmithKline]	0.5 mL prefilled syringe	≥6 mos	NR	No	IM
FluLaval Quadrivalent [ID Biomedical Corp. of Quebec]	0.5 mL prefilled syringe	≥6 mos	NR	No	IM
	5.0 mL multi-dose vial	≥6 mos	<25	No	IM
Fluzone Quadrivalent [Sanofi Pasteur]	0.25 mL prefilled syringe	6 through 35 mos	NR	No	IM
	0.5 mL prefilled syringe	≥3 yrs	NR	No	IM
	0.5 mL single-dose vial	≥3 yrs	NR	No	IM
	5.0 mL multi-dose vial	≥6 mos	25	No	IM
IIV QUADRIVALENT, STANDARD-DOSE,	CELL CULTURE-BASED (ccIIV4)	-	-	-	-
Flucelvax Quadrivalent [Seqirus]	0.5 mL prefilled syringe	≥4 yrs	NR	No	IM
	5.0 mL multi-dose vial	≥4 yrs	25	No	IM
IIV QUADRIVALENT, STANDARD-DOSE, I	NTRADERMAL (Intradermal IIV	(4)	-	-	-
Fluzone Intradermal Quadrivalent [Sanofi Pasteur]	0.1 mL single-dose prefilled micro-injection system	18 through 64 yrs	NR	No	ID
IIV TRIVALENT, STANDARD-DOSE (SD-II	V3)				
Afluria [Seqirus]	0.5 mL prefilled syringe	≥5 yrs	NR	No	IM
	5.0 mL multi-dose vial	≥5 yrs (needle/syringe) 18 through 64 yrs (jet injector)	24.5	No	IM
Fluvirin [Seqirus]	0.5 mL prefilled syringe	≥4 yrs	≤1	Yes*	IM
	5.0 mL multi-dose vial	≥4 yrs	25	No	IM
ADJUVANTED IIV TRIVALENT, STANDAR	D-DOSE (aIIV3)			-	-
Fluad [Seqirus]	0.5 mL prefilled syringe	≥65 yrs	NR	Yes*	IM
IIV TRIVALENT HIGH-DOSE (HD-IIV3)	-	•	-	-	<u></u>
Fluzone High-Dose [Sanofi Pasteur]	0.5 mL prefilled syringe	≥65 yrs	NR	No	IM

INACTIVATED INFLUENZA VACCINES (IIVs)

Abbreviations: ID = intradermal; IM = intramuscular; NR = not relevant (does not contain thimerosal); mos = months; yrs = years. *Syringe tip cap may contain natural rubber latex

IIV Hemagglutinin Content

- Intramuscular SD-IIVs contain 15µg of HA per virus (45 µg total for SD-IIV3s and 60 µg total for SD-IIV4s) per 0.5 mL dose.
- Fluzone High-Dose (HD-IIV3) contains 60µg of HA per virus (180µg total) per 0.5 mL dose.
- Fluzone Intradermal Quadrivalent (intradermal IIV4) contains 9µg of each HA per virus (36µg total) per 0.1 mL dose.

IIV Administration

- IIVs are administered intramuscularly (IM), with the exception of Fluzone Intradermal Quadrivalent. For IM vaccines:
 - Adults and older children: the deltoid is the preferred site;
 - Infants and younger children: the anterolateral thigh is the preferred site.
 - Detailed guidance for administration sites and needle length is available in *Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP)* at <u>https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html</u>
- Afluria and Afluria Quadrivalent are licensed for intramuscular administration via jet injector (the Pharmajet Stratis), for persons aged 18-64 years only.
- Fluzone Intradermal Quadrivalent is administered intradermally, preferably over the deltoid muscle, using the included delivery system.

IIV Contraindications and Precautions

Contraindications:

- History of severe allergic reaction to the vaccine or any of its components
 - ACIP recommends that persons with egg allergy of any severity receive influenza vaccine (see *Persons with a History of Egg Allergy*, above)
 - Information about vaccine components is located in package inserts from each manufacturer.

Precautions:

- Moderate to severe acute illness with or without fever.
- Guillain–Barré syndrome within 6 weeks following a previous dose of influenza vaccine.

TRADE NAME [MANUFACTURER]	PRESENTATION	AGE INDICATION	MERCURY, μG/0.5ML	LATEX	ROUTE	
Flublok Quadrivalent (RIV4) [Protein Sciences]	0.5 mL prefilled syringe	≥18 yrs	NR	No	IM	
Flublok (RIV3) [Protein Sciences]	0.5 mL single-dose vial	≥18 yrs	NR	No	IM	

Abbreviations: IM = intramuscular; NR = not relevant (does not contain thimerosal); yrs = years.

<u>RIV Hemagglutinin Content</u>

 RIVs contain 45µg of HA derived from each vaccine virus per 0.5mL dose (135µg total for RIV3 and 180 µg total for RIV4).

<u>RIV Administration</u>

- RIV is administered intramuscularly.
- Adults: deltoid is the preferred site.
- Detailed guidance for administration sites and needle length is available in *Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP)* at <u>https://www.cdc.gov/vaccines/hcp/acip-recs/general-</u> <u>recs/index.html</u>

<u>RIV Contraindications and Precautions</u>

Contraindications:

- History of severe allergic reaction to any component of the vaccine.
 - Information about vaccine components is located in package inserts from the manufacturer.

Precautions:

- Moderate to severe acute illness with or without fever.
- Guillain–Barré syndrome within 6 weeks following a previous dose of influenza vaccine.

LIVE ATTENUATED INFLUENZA VACCINE (LAIV4)

NOTE: LAIV4 is not recommended for use in any population for 2017-18. Content provided for information only.

TRADE NAME [MANUFACTURER]	PRESENTATION	AGE INDICATION	MERCURY, μG/0.5ML	LATEX	ROUTE
FluMist Quadrivalent (LAIV4) [MedImmune]	0.2 mL single-dose prefilled intranasal sprayer	2 through 49 yrs	NR	No	NAS

Abbreviations: NAS = intranasal; NR = not relevant (does not contain thimerosal); yrs = years.

LAIV Administration

LAIV is not recommended for use in any population for

2017-18. Providers who use it should note the following:

- LAIV is administered intranasally using the supplied prefilled, single-use sprayer containing 0.2 mL of vaccine.
 - Half of the total sprayer contents is sprayed into the first nostril while the recipient is in the upright position.
 - The attached divider clip is removed and the second half of the dose administered into the other nostril.
- If the vaccine recipient sneezes immediately after administration, the dose should not be repeated.
- If nasal congestion impedes delivery of the vaccine to the nasopharyngeal mucosa, deferral should be considered, or another age-appropriate vaccine should be administered.

VACCINE ABBREVIATIONS

- IIV = Inactivated Influenza Vaccine.
 - **IIV3** = Trivalent Inactivated Influenza Vaccine;
 - **IIV4** = Quadrivalent Inactivated Influenza Vaccine.
- **RIV** = Recombinant Influenza Vaccine.
 - **RIV3** = Trivalent Recombinant Influenza Vaccine;
 - **RIV4** = Quadrivalent Recombinant Influenza Vaccine.
- LAIV4 = Quadrivalent Live Attenuated Influenza Vaccine
- IIV, RIV, and LAIV denote vaccine categories; numeric suffix denotes number of antigens in the vaccine,
- When referring specifically to adjuvanted vaccine, the prefix "a" is used (e.g., **allV3**).
- When referring specifically to cell culture-based vaccine, the prefix "cc" is used (e.g., ccIIV4).
- When referring specifically to High-dose vs. Standard-dose vaccines, the prefixes "HD-" and "SD-" are used (e.g., HD-IIV3 vs. SD-IIV3 and SD-IIV4).

LAIV Contraindications and Precautions

Contraindications:

- History of severe allergic reaction to any vaccine component or after previous dose of any influenza vaccine;
 - Information about vaccine components is located in package inserts from the manufacturer.
- Concomitant aspirin or salicylate-containing therapy in children and adolescents;
- Children aged 2 through 4 years who have received a diagnosis of asthma or whose parents or caregivers report that a health care provider has told them during the preceding 12 months that their child had wheezing or asthma or whose medical record indicates a wheezing episode has occurred during the preceding 12 months;
- Children and adults who are immunocompromised due to any cause (including immunosuppression caused by medications or by HIV infection);
- Close contacts and caregivers of severely immunosuppressed persons who require a protected environment;
- Pregnancy;
- Receipt of influenza antiviral medication within previous 48 hours.

Precautions:

- Moderate to severe acute illness with or without fever;
- History of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine;
- Asthma in persons aged ≥5 years;
- Other underlying medical conditions that might predispose to complications attributable to severe influenza (e.g., chronic pulmonary, cardiovascular [except isolated hypertension], renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus).