

AIPO VFC PEDIATRIC INFLUENZA VACCINE 2019-2020

**6–35
MONTHS
OLD**



Fluzone® Quadrivalent
Sanofi Pasteur, Inc.
0.25 mL single-dose syringe
 NDC 49281-0519-25

DOUBLE-CHECK THE DOSE!

	6–35 months	3+ years
Fluzone® syringes	0.25mL or 0.5mL	0.5mL
FluLaval® syringes Fluarix® syringes	0.5mL	0.5mL

Administer the entire dose to appropriate age—
do not split 0.5mL dose for multiple uses.

**6 MONTHS
& OLDER**



Fluarix® Quadrivalent
GlaxoSmithKline Biologicals
0.5 mL single-dose syringe
 NDC 58160-0896-52



FluLaval® Quadrivalent
GlaxoSmithKline Biologicals
0.5 mL single-dose syringe
 NDC 19515-0906-52



FluLaval® Quadrivalent
GlaxoSmithKline Biologicals
5.0 mL** multi-dose vial
NDC 19515-0897-11



Fluzone® Quadrivalent
Sanofi Pasteur, Inc.
0.5 mL single-dose syringe
 NDC 49281-0419-50



Fluzone® Quadrivalent
Sanofi Pasteur, Inc.
0.5 mL single-dose vial
NDC 49281-0419-10



Fluzone® Quadrivalent
Sanofi Pasteur, Inc.
5.0 mL** multi-dose vial
NDC 49281-0631-15

**4 YEARS
& OLDER**



Flucelvax® Quadrivalent
Sequirus
0.5 mL single-dose syringe
 NDC 70461-0319-03



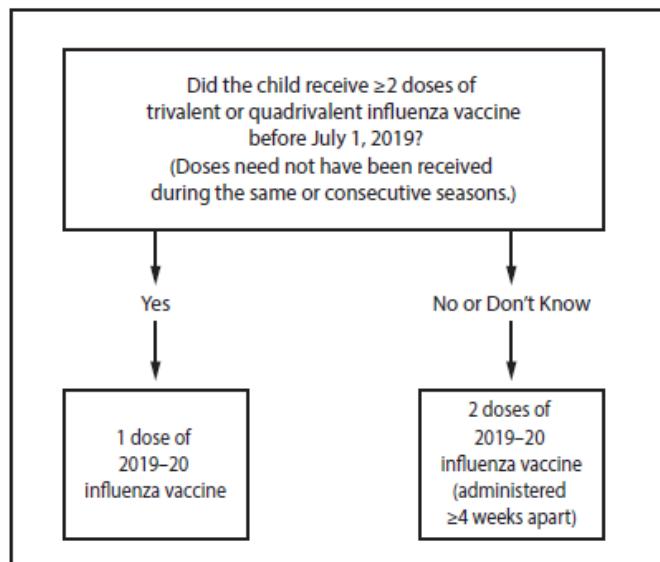
Flucelvax® Quadrivalent
Sequirus
5.0 mL** multi-dose vial
NDC 70461-0419-10

**2–49
YEARS OLD
& HEALTHY**



FluMist® Quadrivalent
MedImmune Vaccines, Inc.
0.2 mL single-dose nasal sprayer
 NDC 66019-0306-10

FIGURE. Influenza vaccine dosing algorithm for children aged 6 months through 8 years* — Advisory Committee on Immunization Practices, United States, 2019–20 influenza season



** Multidose vials contain small amounts of preservative (usually less than 25 mcg Hg/0.5mL mercury content). Do not use any more than the indicated number of doses on the MDV.

**STORE ALL INFLUENZA
VACCINES IN THE
REFRIGERATOR.**

**VFC Questions:
Call 877-491-5741
602-364-3642**



ARIZONA DEPARTMENT
OF HEALTH SERVICES

* 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.

Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP)—United States, 2019-20

Summary of Recommendations

For additional information: *MMWR Recomm Rep* 2019;68(No. RR-3), at <https://www.cdc.gov/vaccines/hcp/acip-recom/vacc-specific/flu.html>.
This document is available in HTML format at <https://www.cdc.gov/flu/professionals/acip/summary/summary-recommendations.htm>.

GROUPS RECOMMENDED FOR VACCINATION

- Routine annual influenza vaccination is recommended for all persons aged ≥6 months who do not have contraindications.
- A licensed vaccine appropriate for age and health status should be used. Consult package information for age indications.
- Emphasis should be placed on vaccination of high-risk groups and their contacts/caregivers. When vaccine supply is limited, vaccination efforts should focus on delivering vaccination to (no hierarchy implied by order listed):
 - Children aged 6 through 59 months
 - Adults aged ≥50 years
 - Persons with chronic pulmonary (including asthma), cardiovascular (excluding isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus)
 - Persons who are immunocompromised due to any cause, including (but not limited to) 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 who might be at risk for Reye syndrome after influenza infection.
 - Residents of nursing homes and other long-term care facilities
 - American Indians/Alaska Natives
 - Persons who are extremely obese (BMI ≥40 for adults)
 - Caregivers and contacts of those at risk:
 - Health care personnel, including all paid and unpaid persons working in health-care settings who have potential for exposure to patients and/or to infectious materials, whether or not directly involved in patient care;
 - 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;
 - Household contacts and caregivers of persons with medical conditions associated with increased risk of severe complications from influenza.

TIMING OF VACCINATION

- Vaccination should be offered by the end of October; however, vaccination should continue to 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 (see Figure) should receive their first dose as soon as possible after vaccine becomes available, and the second dose ≥4 weeks later.

ADULTS AGED ≥65 YEARS

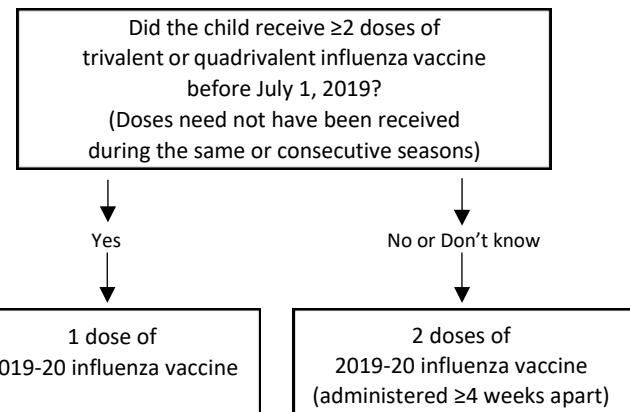
- Persons aged ≥65 years may receive any age-appropriate IIV (standard- or high-dose, trivalent or quadrivalent, adjuvanted or unadjuvanted) or RIV4.
- High-dose IIV3 exhibited superior efficacy over a comparator standard-dose IIV3 in a large randomized trial, and may provide better protection than standard dose IIV3 for this age group.
- However, vaccination should not be delayed to find a particular product if an appropriate one is available.

VOLUME PER DOSE FOR CHILDREN AND ADULTS

- Four IIV4s are licensed for ages 6 through 35 months. Dose volumes differ for these vaccines for this age group. Children aged 6 through 35 months may receive (intramuscularly):
 - 0.25mL of Afluria Quadrivalent, or
 - 0.5mL of Fluarix Quadrivalent, or
 - 0.5mL of FluLaval Quadrivalent, or
 - **Either** 0.25mL **or** 0.5 mL of Fluzone Quadrivalent.
- Children aged 3 through 17 years may receive 0.5mL of an age-appropriate intramuscular IIV formulation.
- Adults aged ≥18 years may receive 0.5mL intramuscularly of an age-appropriate IIV or RIV4.
- If a 0.25mL intramuscular dose is administered to a person ≥36 months of age:
 - If the error is discovered immediately, an additional 0.25mL 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.
- Healthy non-pregnant persons (see **LAI4 Contraindications and Precautions** on page 4) aged 2 through 49 years may alternatively receive 0.2mL of LAIV4 intranasally (0.1mL per nostril, using the supplied sprayer).

NUMBER OF DOSES NEEDED FOR CHILDREN AGED 6 MONTHS THROUGH 8 YEARS

- Determine the number of doses needed based on child's age at time of first dose of 2019–20 influenza vaccine and number of doses of influenza vaccine received in previous seasons
 - Persons aged ≥9 years need only one dose for 2019–20.
 - For children aged 6 months through 8 years, determine the number of doses needed as shown below.
 - For children needing two doses, the second dose is recommended even if the child turns age 9 years between dose 1 and dose 2.
 - Children aged <6 months should not receive influenza vaccine.



PREGNANT WOMEN

- All women who are pregnant or who might be pregnant during the influenza season should receive influenza vaccine.
 - An age-appropriate IIV or RIV4 may be used.
 - LAIV4 should not be used during pregnancy.
- Influenza vaccine can be administered at any time during pregnancy.

IMMUNOCOMPROMISED PERSONS

- Immunocompromised persons should receive an age-appropriate IIV or RIV4.
- LAIV4 should not be used for immunocompromised persons.
- Immune response to vaccines might be blunted in immunocompromised persons, and might be reduced or minimal as a result of medications, chemotherapy, or transplant regimens.
- Timing vaccination during some period either before or after interventions which compromise immunity may be appropriate. The Infectious Diseases Society of America (IDSA) has published guidance concerning the timing of vaccination in relation to such interventions, available at:
<https://academic.oup.com/cid/article/58/3/e44/336537>.

CAREGIVERS AND CONTACTS OF HIGH-RISK PERSONS

- Caregivers and contacts (including those of immunosuppressed persons) may receive any age-appropriate IIV or RIV4.
- LAIV4 may be given to caregivers and contacts of persons who are not severely immunocompromised (i.e., who do not require a protected environment).
- Health care personnel or hospital visitors who receive LAIV4 should avoid providing care for severely immunosuppressed persons requiring a protected environment for 7 days after vaccination.

PERSONS WITH CHRONIC MEDICAL CONDITIONS

- LAIV4 is not recommended for persons with some chronic medical conditions. See ***LAIV4 Contraindications and Precautions*** on Page 4 for more information.

PERSONS WITH 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, RIV4, or LAIV4).
- Persons reporting symptoms other than hives after exposure to egg (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 reactions.
- 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.
- Vaccination with Southern Hemisphere influenza vaccine prior to travel to the Southern Hemisphere may be reasonable; however, only one Southern Hemisphere formulation is licensed by FDA (Fluzone Quadrivalent, Sanofi Pasteur), and it is generally not commercially available in the U.S.

VACCINATION AND INFLUENZA ANTIVIRAL MEDICATIONS

- IIV and RIV4 may be administered to persons receiving influenza antiviral medications for treatment or chemoprophylaxis.
- Influenza antivirals may reduce the effectiveness of LAIV4 if administered from 48 hours before until 2 weeks after vaccination.

ADMINISTRATION OF INFLUENZA VACCINE WITH OTHER VACCINES

- IIVs and RIV4 may be administered concurrently or sequentially with other inactivated or live vaccines.
- Vaccines administered simultaneously should be given at separate anatomic sites.
- LAIV4 may be administered simultaneously with other inactivated or live vaccines. If not given simultaneously, ≥4 weeks should pass between administration of LAIV4 and another live vaccine.
- Immunogenicity and safety of simultaneous or sequential administration of two vaccines containing novel (non-aluminum) adjuvants has not yet been evaluated.

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 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: www.cdc.gov/flu
- CDC FluView: www.cdc.gov/flu/weekly
- Periodic influenza updates: www.cdc.gov/mmwr
- Influenza Antivirals Guidance: www.cdc.gov/flu/professionals/antivirals/summary/clinicians.htm
- For more information, call CDC at (800) 232-4636.

American Academy of Pediatrics (AAP) Guidance

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

Infectious Diseases Society of America (IDSA) Guidance

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

Manufacturer package inserts for U.S.-licensed vaccines

- www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm

VACCINE ABBREVIATIONS

- **IIV** = Inactivated Influenza Vaccine.
 - **IIV3** = Trivalent Inactivated Influenza Vaccine;
 - **IIV4** = Quadrivalent Inactivated Influenza Vaccine.
- **RIV4** = Quadrivalent Recombinant Influenza Vaccine.
- **LAIV4** = Quadrivalent Live Attenuated Influenza Vaccine.
- **aiIV3** refers specifically to adjuvanted IIV3.
- **ccIIV4** refers specifically to cell culture-based IIV4.
- **HD-IIV3** refers specifically to high-dose IIV3.
- **SD-IIV3** and **SD-IIIV4** refer specifically to standard-dose trivalent IIV and standard-dose quadrivalent IIV, respectively.

U.S. INFLUENZA VACCINES FOR THE 2019-20 SEASON

INFLUENZA VACCINE COMPOSITION FOR 2019-20

- 2019-20 influenza vaccines will contain hemagglutinin (HA) derived from influenza viruses antigenically similar to those recommended by FDA.
- Trivalent vaccines will contain
 - an A/Brisbane/02/2018 (H1N1)pdm09-like virus;
 - an A/Kansas/14/2017 (H3N2)-like virus; and
 - a B/Colorado/06/2017-like virus (Victoria lineage).
- Quadrivalent vaccines will contain the same three HA antigens as trivalent vaccines, plus a B/Phuket/3073/2013-like virus (Yamagata lineage).

INACTIVATED INFLUENZA VACCINES (IIVs) and RECOMBINANT INFLUENZA VACCINE (RIV4)

Trade name <i>Manufacturer</i>	Presentation	Age indication	HA, µg/dose (each virus)	Egg-grown virus, Cell culture-grown virus, or Recombinant HA	Adjuvanted Yes/No	Thimerosal Yes/No (If yes, Mercury, µg/0.5mL)
Quadrivalent IIVs (IIV4s)						
Afluria Quadrivalent <i>Seqirus</i>	0.25 mL prefilled syringe* 0.5 mL prefilled syringe* 5.0 mL multidose vial*	6 through 35 mos* ≥3 years* ≥6 mos* (needle/syringe) 18 through 64 yrs (jet injector)	7.5/0.25 mL 15/0.5 mL See note for dosing*	Egg	No	No No Yes (24.5)
Fluarix Quadrivalent <i>GlaxoSmithKline</i>	0.5 mL prefilled syringe	≥6 mos	15/0.5mL	Egg	No	No
FluLaval Quadrivalent <i>GlaxoSmithKline</i>	0.5 mL prefilled syringe 5.0 mL multidose vial	≥6 mos ≥6 mos	15/0.5mL	Egg	No	No Yes (<25)
Flucelvax Quadrivalent <i>Seqirus (cclIV4)</i>	0.5 mL prefilled syringe 5.0 mL multidose vial	≥4 yrs ≥4 yrs	15/0.5mL	Cell	No	No Yes (25)
Fluzone Quadrivalent <i>Sanofi Pasteur</i>	0.25 mL prefilled syringe† 0.5 mL prefilled syringe† 0.5 mL single-dose vial† 5.0 mL multidose vial†	6 through 35 mos† ≥6 mos† ≥6 mos† ≥6 mos†	7.5/0.25 mL 15/0.5 mL See note for dosing†	Egg	No	No No No Yes (25)
Trivalent IIVs (IIV3s)						
Fluad <i>Seqirus (allIV3)</i>	0.5 mL prefilled syringe	≥65 yrs	15/0.5mL	Egg	Yes	No
Fluzone High-Dose <i>Sanofi Pasteur (HD-IIV3)</i>	0.5 mL prefilled syringe	≥65 yrs	60/0.5mL	Egg	No	No
Quadrivalent RIV (RIV4)						
Flublok Quadrivalent <i>Sanofi Pasteur</i>	0.5 mL prefilled syringe	≥18 yrs	45/0.5mL	Recombinant	No	No

Abbreviations: IIV=inactivated influenza vaccine; RIV=recombinant influenza vaccine; HA=hemagglutinin; mos=months; yrs=years.

*for Afluria Quadrivalent, children aged 6 through 35 mos should receive 0.25mL per dose. Persons ≥36 mos (≥3 yrs) should receive 0.5mL per dose.

†for Fluzone Quadrivalent, children aged 6 through 35 mos may receive either 0.25mL or 0.5mL per dose. Persons ≥36 mos (≥3 yrs) should receive 0.5mL per dose

Administration of IIVs and RIV4

- IIVs and RIV4 are administered intramuscularly (IM):
 - 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 the Best Practice Guidelines of the Advisory Committee on Immunization Practices (ACIP) at <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html>
 - Afluria Quadrivalent is licensed for IM administration via jet injector (the Pharmajet Stratis), for persons aged 18 through 64 years only.
 - RIV4 is licensed for persons aged ≥18 years and should not be used for children aged <18 years.

IIV and RIV4 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 Egg Allergy, above).
 - Information about vaccine components is located in package inserts from each manufacturer.

Precautions:

- Moderate or 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)

Trade name <i>Manufacturer</i>	Presentation	Age indication	Virus count per dose (each virus)	Egg-grown virus, Cell culture-grown virus, or Recombinant HA	Adjuvanted Yes/No	Thimerosal Yes/No (If yes, Mercury, µg/0.2mL)
Quadrivalent LAIV (LAIV4)						
FluMist Quadrivalent AstraZeneca	0.2mL prefilled intranasal sprayer	2 through 49 yrs	10 ^{6.5-7.5} fluorescent focus units/0.2mL	Egg	No	No

Abbreviations: LAIV=live attenuated influenza vaccine; mos=months; yrs=years.

Administration of LAIV4

- LAIV4 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 is present that might interfere with delivery of the vaccine to the nasopharyngeal mucosa, deferral should be considered, or another age-appropriate vaccine should be administered.

LAIV4 Contraindications and Precautions

Contraindications:

- History of severe allergic reaction to any vaccine component or after previous dose of any influenza vaccine;
 - ACIP recommends that persons with egg allergy of any severity receive influenza vaccine (see Persons with Egg Allergy, above).
 - 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 or 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 (excluding isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus).

STORAGE AND HANDLING OF INFLUENZA VACCINES

- In all cases, manufacturer packaging information should be consulted for authoritative guidance regarding storage and handling of influenza vaccines.
- For guidance on specific situations not addressed in packaging materials, contact the manufacturer directly.
- Additional information may also be found in the *Vaccine Storage and Handling Toolkit*, which is available at:
<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>
- In general:
 - 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 frozen should be discarded.
 - Single-dose vials should not be accessed for more than one dose.
 - Multidose 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.
 - Multidose vials may have a labeled Beyond Use Date (BUD) in addition to the expiration date. The BUD specifies the number of days the vaccine may be used once accessed for the first time. If no BUD is provided, the listed expiration date should be used.
 - Package information may also specify a maximum number of doses that should be taken from multidose vials (regardless of remaining volume).