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Date: September 4, 2020

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

Ryan Westergaard, MD, PhD, MPH
State Epidemiologist for Communicable Diseases

Re: The 2020-2021 Advisory Committee on Immunization Practices (ACIP) recommendations for the prevention and control of seasonal influenza with vaccines

Promote Influenza Vaccination

Influenza and SARS-CoV-2 viruses are expected to circulate at the same time during the upcoming 2020-2021 influenza season. In this context, vaccination against influenza will be more important than ever to decrease the overall impact of respiratory illnesses by reducing influenza-associated illnesses, hospitalizations, and deaths, and reducing the burden on the health care system.

During the COVID-19 pandemic, reducing the overall burden of respiratory illnesses is important to protect vulnerable populations at risk for severe illness, the health care system, and other critical infrastructure. Thus, health care providers should begin offering influenza vaccine as soon as product becomes available and should use every opportunity during the influenza vaccination season to administer influenza vaccines to all medically-eligible persons, including;

- *Essential workers*: Including healthcare personnel (including nursing home, long-term care facility, and pharmacy staff) and other critical infrastructure workforce
- *Persons at increased risk for severe illness from COVID-19*: Including adults aged 65 years and older, residents in a nursing home or assisted living facility, and persons of all ages with certain underlying medical conditions. Severe illness from COVID-19 has been observed to disproportionately affect members of certain racial/ethnic minority groups
- *Persons at increased risk for serious influenza complications*: Including infants and young children, children with neurologic conditions, pregnant women, adults aged 65 years and older, and other persons with certain underlying medical conditions

Vaccination should be deferred for persons with suspected or confirmed COVID-19, regardless of whether they have symptoms, until they have met the criteria to discontinue their isolation in order to diminish risk of spread to others at sites of vaccination. Consider your facility's influenza vaccine campaign to be a dress rehearsal for potential COVID-19 vaccine delivery. Continue to offer seasonal influenza vaccine as long as influenza viruses are circulating and to schedule immunization clinics

throughout the influenza season into 2021 because influenza was detected among Wisconsin residents during 51 weeks of 2019 (the most current year for which we have complete data).

Safe Delivery of Vaccine

- How and where people receive their influenza vaccine may need to change due to the COVID-19 pandemic. For example, clinics could consider drive-through or curbside delivery of vaccine in order to maintain physical distancing and should use appropriate personal protective equipment while administering vaccines. Walk-in influenza vaccine clinics may need to be replaced with scheduled times to comply with local social distancing requirements.
- The Centers for Disease Control and Prevention has released Vaccination Guidance During a Pandemic. This guidance is intended to help immunization providers in a variety of clinical and alternative settings with the safe administration of vaccines during the COVID-19 pandemic. This guidance will be continually reassessed and updated based on the evolving epidemiology of COVID-19 in the United States.
- The Centers for Disease Control and Prevention has also released Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations.

The full ACIP Recommendations

The 2020-2021 ACIP recommendations for the prevention and control of seasonal influenza with vaccines were formally issued on August 21, 2020. This document can be downloaded from the MMWR website at: https://www.cdc.gov/mmwr/volumes/69/rr/rr6908a1.htm.

Updated ACIP information regarding the vaccine supply and timing of distribution of influenza vaccine that affect the target groups will be posted on the Centers for Disease Control and Prevention (CDC) website at www.cdc.gov/flu as needed. The 2020-2021 Vaccine Information Statements (VIS) for Influenza are available at http://www.cdc.gov/vaccines/hcp/vis/index.html. Guidance for vaccine planning during the COVID-19 pandemic is available at https://www.cdc.gov/vaccines/pandemic-guidance/index.html.

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 influenza season and the months leading up to it. 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.

Vaccines available during the 2020-2021 season are (Table 1):

- Quadrivalent inactivated influenza vaccine (IIV4)
  - Sanofi Pasteur (Fluzone Quadrivalent)
  - GlaxoSmithKline (Fluarix Quadrivalent)
  - GlaxoSmithKline (FluLaval Quadrivalent)
  - Seqirus (Afluria Quadrivalent)
  - Sanofi Pasteur (Fluzone High-Dose Quadrivalent)
- Quadrivalent cell-culture based influenza vaccine (ccIIV4): Seqirus (Flucelvax Quadrivalent)
- Live-attenuated influenza vaccine, quadrivalent (LAIV4): AstraZeneca (FluMist Quadrivalent)
- Adjuvanted inactivated influenza vaccine, trivalent (aIIV3): Seqirus (Fluad)
- Adjuvanted inactivated influenza vaccine, quadrivalent (aIIV4): Sequirus (Fluad Quadrivalent)
- Recombinant hemagglutinin (HA) influenza vaccine (RIV4): Sanofi Pasteur (FluBlok Quadrivalent), for persons with egg allergy of any severity

During the 2020-2021 influenza season, we recommend that providers begin offering vaccination as soon as vaccine is available (by October, if possible). Vaccination of all persons aged ≥6 months continues to be recommended. Not all influenza vaccines are likely to be uniformly available in any given practice setting or geographic locality. 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.

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. HealthMap Vaccine Finder may be used to identify a location (e.g., clinic or community pharmacy) to receive influenza vaccine: http://flushot.healthmap.org/.

The 2020-2021 ACIP Recommendations include two principal updates:

Summary of updates to the ACIP Recommendations
The principal updates to the 2020-2021 ACIP recommendations for the prevention and control of seasonal influenza with vaccines are**:**

1. Trivalent egg-based vaccine will contain:
   - A/Guangdong-Maonan/SWL1536/2019 (H1N1)pdm09-like virus (updated).
   - A/Hong Kong/2671/2019 (H3N2)-like virus (updated).
   - B/Washington/02/2019 (B/Victoria lineage)-like virus (updated).

Quadrivalent egg-based vaccines (including FluMist), which protect against a second lineage of B viruses, will contain:
   - The three recommended viruses above, plus B/Phuket/3073/2013-like (Yamagata lineage) virus.

Cell- or recombinant-based vaccines will contain:
   - A/Hawaii/70/2019 (H1N1)pdm09-like virus (updated).
   - A/Hong Kong/45/2019 (H3N2)-like virus (updated).
   - B/Washington/02/2019 (B/Victoria lineage)-like virus (updated).
   - B/Phuket/3073/2013-like (Yamagata lineage) virus.

Fluad (adjuvanted influenza vaccine) will be the only trivalent vaccine available this season. All others will be quadrivalent formulation.

2. Two new influenza vaccine licensures are described:
   - In November 2019, FDA licensed Fluzone High-Dose Quadrivalent (HD-IIV4). Fluzone High-Dose Quadrivalent is approved for use in persons aged ≥65 years. For the 2020–21 season, Fluzone High-Dose Quadrivalent is expected to replace the previously available trivalent formulation of Fluzone High-Dose (HD-IIV3). The dose volume for Fluzone High-Dose Quadrivalent (0.7 mL) is slightly higher than that of trivalent Fluzone High-Dose (0.5 mL). Fluzone High-Dose Quadrivalent, like Fluzone High-Dose, contains 4 times the amount of HA per vaccine virus in each dose compared with standard-dose inactivated influenza vaccines (60 μg per virus, versus 15 μg in standard-dose IIVs).
   - In February 2020, FDA licensed Fluad Quadrivalent (aIIV4). Fluad Quadrivalent is approved for use in persons aged ≥65 years. For the 2020–21 season, both Fluad Quadrivalent and the previously licensed trivalent formulation of Fluad (aIIV3) are expected to be available. Fluad Quadrivalent, like Fluad, contains the adjuvant MF59.

Influenza vaccination of children aged 6 months through 8 years
1. 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 ≥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

1. 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).
2. 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.
3. Information about influenza vaccination during pregnancy and guidance on how to address concerns that patients may have about influenza vaccination is available at: https://www.cdc.gov/flu/professionals/vaccination/vaccination-possible-safety-signal.html

Influenza vaccination of persons with a history of egg allergy

For the 2020-2021 influenza season, ACIP recommends the following:

1. Persons with a history of egg allergy who have experienced only hives after exposure to egg should receive influenza vaccine. Any licensed, recommended and age-appropriate influenza vaccine (i.e., any IIV, RIV4 or LAIV4) that is otherwise appropriate for the recipient's age and health status may be used.
2. Persons who report having had reactions to egg involving symptoms other than urticaria (e.g., angioedema or swelling, respiratory distress, lightheadedness, or recurrent vomiting) or who required epinephrine or another emergency medical intervention may similarly receive any licensed, recommended influenza vaccine (i.e., any IIV, RIV4, or LAIV4) that is otherwise appropriate for their age and health status. If a vaccine other than ccIIV4 or RIV4 is used, the selected vaccine should be administered in an inpatient or outpatient medical setting (including but not necessarily limited to hospitals, clinics, health departments, and physician offices). Vaccine administration should be supervised by a health care provider who is able to recognize and manage severe allergic reactions.
3. A previous severe allergic reaction to influenza vaccine, regardless of the component suspected of being responsible for the reaction, is a contraindication to future receipt of the vaccine.

If you have any questions, please call the Regional Immunization Program Representative in your area:

Jim Zanto	Eau Claire Regional Office	715-836-2499
Susan Nelson	Green Bay Regional Office	920-448-5231
Wilmot Valhmu	Madison Central Office	608-266-0008
Jacqueline Sills-Ware	Milwaukee Regional Office	414-227-4876
Monica Thakur	Milwaukee Regional Office	414-227-3995
Christie Oestreich	Rhinelander Regional Office	715-365-2709

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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, 2020-2021 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, quadrivalent (IIV4), standard dose, egg based†						
Afluria Quadrivalent	Seqirus	0.25 mL PFS§	--	6–35 mos	IM¶	7.5 µg/0.25 mL
		0.5 mL PFS	--	≥3 yrs	IM¶	15 µg/0.5 mL
		5.0 mL MDV§	24.5	≥6 mos (needle/ syringe) 18-64 yrs (jet injector)	IM¶	
Fluarix Quadrivalent	GlaxoSmithKline	0.5 mL PFS	--	≥6 mos	IM¶	15 µg/0.5 mL
FluLaval Quadrivalent	GlaxoSmithKline	0.5 mL PFS	--	≥6 mos	IM¶	15 µg/0.5 mL
Fluzone Quadrivalent	Sanofi Pasteur	0.5 mL PFS**	--	≥6 mos	IM¶	15 µg/0.5 mL
		0.5 mL SDV	--	≥6 mos	IM¶	
		5.0 mL MDV	25	≥6 mos	IM¶	
Inactivated influenza vaccine, cell culture-based (ccIIV4), standard dose						
Flucelvax Quadrivalent	Seqirus	0.5 mL PFS	--	≥4 yrs	IM¶	15 µg/0.5 mL
		5.0 mL MDV	25	≥4 yrs	IM¶	
Adjuvanted inactivated influenza vaccine, trivalent (aIIV4), standard dose, egg based†						
Fluad	Seqirus	0.5 mL PFS	--	≥65 yrs	IM¶	15 µg/0.5 mL
Inactivated influenza vaccine, trivalent (HD-IIV4), high dose, egg based†						
Fluzone High-Dose	Sanofi Pasteur	0.7 mL PFS	--	≥65 yrs	IM¶	60 µg/0.7 mL
Recombinant influenza vaccine, quadrivalent (RIV4)						
FluBlok Quadrivalent	Sanofi Pasteur	0.5 mL PFS	--	≥18 yrs	IM¶	45 µg/0.5 mL
Live attenuated influenza vaccine, quadrivalent (LAIV4), egg based†						
FluMist Quadrivalent	AstraZeneca	0.2 mL prefilled single-use intranasal sprayer	--	2–49 yrs	NAS	$10^{6.5\text{-}7.5}$ fluorescent focus units/0.2 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

Abbreviations: ACIP = Advisory Committee on Immunization Practices; FDA = Food and Drug Administration; HA = hemagglutinin; IIV3 = inactivated influenza vaccine, trivalent; IIV4 = inactivated influenza vaccine, quadrivalent; IM = intramuscular; LAIV4 = live attenuated influenza vaccine, quadrivalent; MDV = multidose vial; NAS = intranasal; PFS = prefilled syringe; RIV4 = recombinant influenza vaccine, quadrivalent; SDV = single-dose vial.

* Vaccination providers should consult FDA-approved prescribing information for 2020–21 influenza vaccines for the most complete and updated information, including (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/approved-products/vaccines-licensed-use-united-states. Availability and characteristics of specific products and presentations might change and/or differ from what is described in this table and in the text of this report.

† History of severe allergic reaction (e.g., anaphylaxis) to egg is a labeled contraindication to the use of most IIVs and LAIV4. However, ACIP recommends that persons with a history of egg allergy may receive any licensed, recommended influenza vaccine that is otherwise appropriate for their age and health status. Those who report

having had reactions to egg involving symptoms other than urticaria (e.g., angioedema or swelling, respiratory distress, lightheadedness, or recurrent emesis) or who required epinephrine or another emergency medical intervention should be vaccinated in an inpatient or outpatient medical setting (including, but not necessarily limited to, hospitals, clinics, health departments, and physician offices) supervised by a health care provider who is able to recognize and manage severe allergic reactions, if a vaccine other than ccIIV4 or RIV4 is used.

[§] The dose volume for Afluria Quadrivalent is 0.25 mL for children aged 6 through 35 months and 0.5 mL for persons aged ≥3 years.

[¶] IM-administered influenza vaccines should be given by needle and syringe only, with the exception of the MDV presentation of Afluria Quadrivalent, 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 guidance regarding site selection and needle length for intramuscular administration is available in the ACIP General Best Practice Guidelines for Immunization, available at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf.

** Fluzone Quadrivalent is currently licensed for ages 6 through 35 months at either 0.25 mL or 0.5 mL per dose; however, 0.25-mL prefilled syringes are not expected to be available for the 2020–21 influenza season. If a prefilled syringe of Fluzone Quadrivalent is used for a child in this age group, the dose volume will be 0.5mL per dose.

TABLE 2. Contraindications and precautions to the use of influenza vaccines—United States, 2020-2021 influenza season*

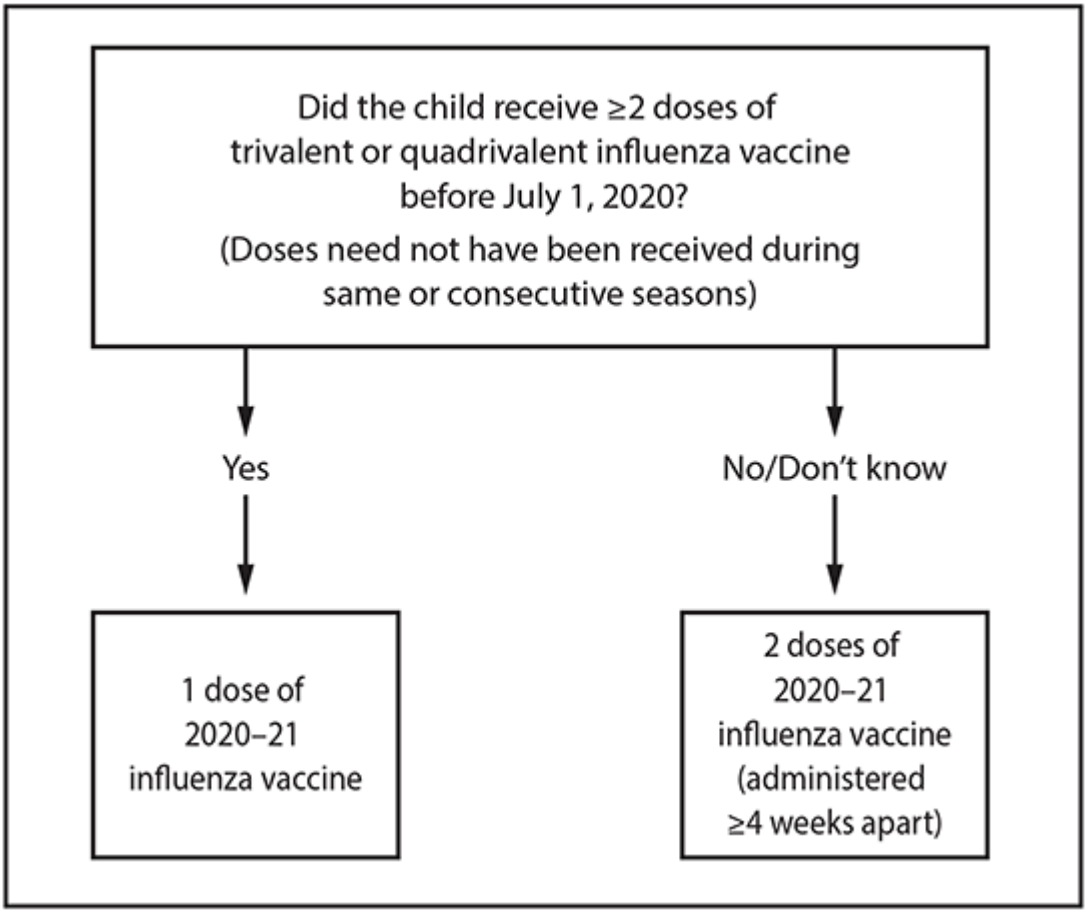
Vaccine	Contraindications	Precautions
IIV3 and IIV4	History of severe allergic reaction to any component of the vaccine[†] or to a previous dose of any influenza vaccine	Moderate or severe acute illness with or without fever History of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine
RIV4	History of severe allergic reaction to any component of the vaccine	Moderate or severe acute illness with or without fever History of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine
LAIV	History of severe allergic reaction to any component of the vaccine[†] or to a previous dose of any influenza vaccine[§] 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 but not limited to immunosuppression caused by medications, congenital or acquired immunodeficiency states, HIV infection, anatomic asplenia, or functional asplenia (e.g., due to sickle cell anemia) Close contacts and caregivers of severely immunosuppressed persons who require a protected environment 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, precious 5 days for peramivir, and previous 17 days for baloxavir[**]	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 after wild-type influenza infection (e.g., chronic pulmonary, cardiovascular [except isolated hypertension], renal, hepatic, neurologic, hematologic, or metabolic disorders [including diabetes mellitus])

Abbreviations: ACIP = Advisory Committee on Immunization Practices; ccIIV4 = cell culture–based inactivated influenza vaccine; CSF = cerebrospinal fluid; FDA = Food and Drug Administration; IIV3 = inactivated influenza vaccine, trivalent; IIV4 = inactivated influenza vaccine, quadrivalent; LAIV4 = live-attenuated influenza vaccine, quadrivalent; RIV4 = recombinant influenza vaccine, quadrivalent.

* Vaccination providers should check FDA-approved prescribing information for 2020–21 influenza vaccines for the most complete and updated information, including (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/approved-products/vaccines-licensed-use-united-states.

† History of severe allergic reaction (e.g., anaphylaxis) to egg is a labeled contraindication to the use of most IIVs and LAIV4. However, ACIP recommends that persons with a history of egg allergy may receive any licensed, recommended influenza vaccine that is otherwise appropriate for their age and health status. Those who report having had reactions to egg involving symptoms other than urticaria (e.g., angioedema or swelling, respiratory distress, lightheadedness, or recurrent emesis) or who required epinephrine or another emergency medical intervention should be vaccinated in an inpatient or outpatient medical setting (including, but not necessarily limited to, hospitals, clinics, health departments, and physician offices), supervised by a health care provider who is able to recognize and manage severe allergic reactions, if a vaccine other than ccIIV4 or RIV4 is used.
§ Labeled contraindication noted in package insert.
¶ Age-appropriate injectable vaccines are recommended for persons with cochlear implant due to the potential for CSF leak, which might exist for some 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 LAIV4 in context of influenza antivirals has not been studied; however, interference with activity of LAIV4 is biologically plausible, and this possibility is noted in the package insert for LAIV4. In the absence of data supporting an adequate minimum interval between influenza antiviral use and LAIV4 administration, the intervals provided are based on the half-life of each antiviral. The interval between influenza antiviral receipt and LAIV4 for which interference might potentially occur might be further prolonged in the presence of medical conditions that delay medication clearance (e.g., renal insufficiency). Influenza antivirals might also interfere with LAIV4 if initiated within 2 weeks after vaccination. Persons who receive antivirals during the period starting with the specified time before receipt of LAIV4 through two weeks after receipt of LAIV4 should be revaccinated with an age-appropriate IIV or RIV4.

FIGURE 1. Influenza vaccine dosing algorithm for children aged 6 months through 8 years* – Advisory Committee on Immunization Practices, United States, 2020-2021 influenza season



* 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.