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Date: October 2, 2013

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

From: Jeffrey P. Davis, MD, Chief Medical Officer and State Epidemiologist for Communicable Diseases and Emergency Response

Jonathan L. Temte, MD, PhD
Chair, Wisconsin Council on Immunization PracticesJay A. Gold, MD, JD, MPH
Wisconsin Adult Immunization Coalition

Re: 2013-2014 Recommendations for Use of Seasonal Influenza Vaccines

Summary of Updates to the Recommendations**The 2013-2014 Advisory Committee on Immunization Practices (ACIP) recommendations include four principal updates:**

1. The composition of the 2013-2014 trivalent influenza vaccine includes the following three influenza virus strains: A/California/7/2009 (H1N1)-like virus, an H3N2 virus antigenically like the cell-propagated prototype virus A/Victoria/361/2011 (H3N2)-like, and B/Massachusetts/2/2012-like virus. Quadrivalent vaccines will include an additional vaccine virus, a B/Brisbane/60/2008-like virus.

2. Several new, recently-licensed vaccines will be available for the 2013-2014 season and are acceptable alternatives to other licensed vaccines indicated for their respective age groups when otherwise appropriate:

- A quadrivalent live attenuated influenza vaccine (LAIV4; Flumist[®] Quadrivalent [MedImmune]) replaces the trivalent (LAIV3) formulation. Flumist[®] Quadrivalent is indicated for healthy, nonpregnant persons aged 2 through 49 years;
- A quadrivalent inactivated influenza vaccine (IIV4; Fluarix[®] Quadrivalent [GlaxoSmithKline]) is available, in addition to the previous trivalent formulation. Fluarix[®] Quadrivalent is indicated for persons aged 3 years and older;
- A quadrivalent inactivated influenza vaccine (IIV4; Fluzone[®] Quadrivalent [Sanofi Pasteur]) is available, in addition to the previous trivalent formulation. Fluzone[®] Quadrivalent is indicated for persons aged 6 months and older;
- A trivalent cell culture-based inactivated influenza vaccine (ccIIV3; Flucelvax[®] [Novartis Vaccines and Diagnostics]), which is indicated for persons aged 18 years and older; and
- A recombinant hemagglutinin (HA) vaccine (RIV3; FluBlok[®] [Protein Sciences]), which is indicated for persons aged 18 through 49 years.

3. RIV3, an egg-free vaccine, is now an option for vaccination of persons aged 18 through 49 years with egg allergy of any severity.

4. For persons with egg allergy who have no known history of egg exposure but for whom results suggestive of egg allergy have been obtained on previous allergy testing, consultation with a physician with expertise in the management of allergic conditions is recommended before vaccination.

The full recommendations follow.

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dhs.wisconsin.gov**Full Recommendations**

The 2013-2014 Advisory Committee on Immunization Practices (ACIP) recommendations for the prevention and control of seasonal influenza with vaccines were formally issued on September 20, 2013. This document can be downloaded from the MMWR website at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6207a1.htm?s_cid=rr6207a1_w. Updated ACIP information on 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 2013-2014 Vaccine Information Statements (VIS) for Influenza are available at www.cdc.gov/vaccines/pubs/vis/default.htm.

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.

Five companies are producing seasonal trivalent inactivated influenza vaccine (IIV3) formulated for the 2013-2014 influenza season. The name of the company and vaccine(s) that they produce are: Sanofi Pasteur (Fluzone[®], Fluzone High-Dose[®], and Fluzone Intradermal[®]), Novartis Vaccines and Diagnostics (Flucelvax[®] and Fluvirin[®]), GlaxoSmithKline (Fluarix[®]), CSL Limited (Afluria[®]), and ID Biomedical Corporation of Quebec (FluLaval[®]). A recombinant hemagglutinin (HA) vaccine (RIV3; FluBlok[®]), produced by Protein Sciences, is an egg-free vaccine option for persons with egg allergy of any severity. Three companies are producing seasonal quadrivalent inactivated influenza vaccine (IIV4) formulated for the 2013-2014 influenza season. The name of the company and vaccine that they produce are: Sanofi Pasteur (Fluzone[®] Quadrivalent), GlaxoSmithKline (Fluarix[®] Quadrivalent), and ID Biomedical Corporation of Quebec (FluLaval[®] Quadrivalent). MedImmune, Inc. is manufacturing the live-attenuated seasonal influenza vaccine (LAIV4) FluMist[™] for the U.S. market (Table).

During the 2013-2014 influenza season we recommend that providers begin offering vaccination as soon as vaccine is available and, if possible, by the end of October. Vaccination of all persons aged ≥ 6 months continues to be recommended. It is also important to continue to offer seasonal influenza vaccine throughout the influenza season and to schedule immunization clinics throughout the influenza season into 2013, because influenza was detected among Wisconsin residents during all but 2 weeks during 2012.

In the event of a shortfall in production or a delay in the delivery of adequate supplies 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 influenza vaccine 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 2013-2014 ACIP recommendations include four principal updates:

1. The composition of the 2013-2014 trivalent influenza vaccine includes the following three influenza virus strains: A/California/7/2009 (H1N1)-like virus, an H3N2 virus antigenically like the cell-propagated prototype virus A/Victoria/361/2011 (H3N2)-like, and B/Massachusetts/2/2012-like virus. Quadrivalent vaccines will include an additional vaccine virus, a B/Brisbane/60/2008-like virus.

2. Several new, recently-licensed vaccines are available for the 2013-2014 season, and are acceptable alternatives to other licensed vaccines indicated for their respective age groups when otherwise appropriate:

- LAIV4, Flumist[®] Quadrivalent (MedImmune) has replaced the trivalent (LAIV3) formulation. Flumist[®] Quadrivalent is indicated for healthy, nonpregnant persons aged 2 through 49 years;
- IIV4, Fluarix[®] Quadrivalent (GlaxoSmithKline) is available, in addition to the previous trivalent formulation. Fluarix[®] Quadrivalent is indicated for persons aged 3 years and older;
- IIV4, Fluzone[®] Quadrivalent (Sanofi Pasteur) is available, in addition to the previous trivalent formulation. Fluzone[®] Quadrivalent is indicated for persons aged 6 months and older;
- ccIIV3, Flucelvax[®] (Novartis Vaccines and Diagnostics) is available and is indicated for persons aged 18 years and older; and
- RIV3, FluBlok[®] (Protein Sciences) is indicated for persons aged 18 through 49 years.

3. RIV3, an egg-free vaccine, is now an option for vaccination of persons aged 18 through 49 years with egg allergy of any severity.

4. For persons with egg allergy who have no known history of egg exposure but for whom results suggestive of egg allergy have been obtained on previous allergy testing, consultation with a physician with expertise in the management of allergic conditions is recommended before vaccination.

Influenza Vaccination for Children Aged 6 Months Through 8 Years

1. All children aged 6 months through 8 years who are recommended for 2 doses 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.

2. If a child receives IIV4 or LAIV4 for one of their two doses but not for both doses, protection against the second influenza B strain may not be sufficient to prevent infection with that strain. However, vaccination should not be delayed if only IIV3 is available.

3. Children aged 6 through 35 months should only receive a 0.25 mL dose of a split-virus vaccine formulation. Currently only Sanofi Pasteur provides this presentation.

Influenza Vaccination for Pregnant Women

1. Vaccination during pregnancy has been shown 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 6 months of life (1).

2. The ACIP and American College of Obstetricians and Gynecologists (ACOG) recommend that all women who are pregnant or who might be pregnant in the upcoming influenza season receive IIV because of an increased risk for serious illness and complications from influenza. LAIV is not recommended for use during pregnancy.

Influenza Vaccination of Persons With a History of Egg Allergy

1. The ACIP has recommended that persons with egg allergy who report only hives after egg exposure should receive RIV3 (if aged 18 through 49 years) or IIV, with several additional safety measures (Figure 2).

2. Persons who report having had reactions to egg involving such symptoms as angioedema, respiratory distress, lightheadedness, or recurrent emesis; or who required epinephrine or another emergency medical intervention, particularly those that occurred immediately or within a short time (minutes to hours) after egg exposure, are more likely to have a serious systemic or anaphylactic reaction upon reexposure to egg proteins. These persons may receive RIV3, if aged 18 through 49 years and there are no other contraindications. If RIV3 is not available or the recipient is not within the indicated age range, these individuals should be referred to a physician with expertise in the management of allergic conditions for further risk assessment.

Additional Influenza Vaccination Recommendations:

1. The first and second doses of vaccine do not have to match; IIV or LAIV can be used to complete the two-dose requirement. Doses should be separated by at least 4 weeks.

2. No preferential recommendation is made for one influenza vaccine product over another for persons for whom more than one product is otherwise appropriate.

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
Cathy Edwards	Milwaukee Regional Office	414-227-3995
Jacqueline Sills-Ware	Milwaukee Regional Office	414-227-4876
Jane Dunbar	Rhineland Regional Office	715-365-2709

Please share this information with other interested parties.

Reference

1. 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.

TABLE. Influenza vaccine information, by age indication – United States, 2013-2014 influenza season*

Vaccine	Trade name	Manufacturer	Presentation	Mercury content (μg Hg/0.5 mL dose)	Ovalbumin content (μg /0.5 mL dose)	Age indications	Route
IIV3	Fluzone	Sanofi Pasteur	0.25 mL prefilled syringe	0.0	— ^{†††}	6-35 mos	IM [†]
			0.5 mL prefilled syringe	0.0	—	≥ 36 mos	IM [†]
			0.5 mL vial	0.0	—	≥ 36 mos	IM [†]
			5.0 mL multidose vial	25.0	—	≥ 6 mos	IM [†]
ccIIV3	Flucelvax	Novartis Vaccines and Diagnostics	0.5 mL prefilled syringe	0	NI ^{§§§}	≥ 18 yrs	IM [†]
IIV3	Fluvirin	Novartis Vaccines and Diagnostics	0.5 mL prefilled syringe	≤ 1.0	≤ 1.0	≥ 4 yrs	IM [†]
			5.0 mL multidose vial	25.0	≤ 1.0		
IIV3	Fluarix	GlaxoSmithKline	0.5 mL prefilled syringe	0	≤ 0.05	≥ 3 yrs	IM [†]
IIV3	FluLaval	ID Biomedical Corporation of Quebec (distributed by GlaxoSmithKline)	5.0 mL multidose vial	< 25.0	≤ 0.3	≥ 3 yrs	IM [†]
IIV3	Afluria	CSL Limited	0.5 mL prefilled syringe	0	≤ 1.0	≥ 9 yrs ^{†††}	IM [†]
			5.0 mL multidose vial	24.5	≤ 1.0		
IIV3 High-Dose	Fluzone High-Dose ^{**}	Sanofi Pasteur	0.5 mL prefilled syringe	0	—	≥ 65 yrs	IM [†]
IIV3	Fluzone	Sanofi Pasteur	0.1 mL	0	—	18-64 yrs	ID [§]

Intradermal	Intradermal††		prefilled microinjection system				
IIV4	Fluarix	GlaxoSmithKline	0.5 mL prefilled syringe	0	≤0.05	≥3 yrs	IM†
IIV4	FluLaval	ID Biomedical Corporation of Quebec (distributed by GlaxoSmithKline)	5.0 mL multidose vial	<25.0	≤0.3	≥3 yrs	IM†
IIV4	Fluzone	Sanofi Pasteur	0.25 mL prefilled syringe	0	—	6-35 mos	IM†
			0.5 mL prefilled syringe	0	—	≥36 mos	IM†
			0.5 mL vial	0	—	≥36 mos	IM†
RIV3	FluBlok	Protein Sciences	0.5 mL vial	0	0	18-49 yrs	IM†
LAIV4	FluMist Quadrivalent§§	MedImmune	0.2 mL prefilled intranasal sprayer	0 (per 0.2 mL)	<0.24 (per 0.2 mL)	2-49 yrs***	INL

Abbreviations: IIV3 = trivalent inactivated influenza vaccine; IIV4 = quadrivalent inactivated influenza vaccine; ccIIV3 = cell culture-based trivalent inactivated influenza vaccine; LAIV4 = quadrivalent live-attenuated influenza vaccine; IM = intramuscular; ID = intradermal; INL = intranasal; NI = not included.

* Vaccination providers should check Food and Drug Administration-approved prescribing information for 2013-2014 influenza vaccines for the most complete and updated information, including (but not limited to) indications, contraindications, and precautions. Package inserts for US-licensed vaccines are available at <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm>.

† For adults and older children, the recommended site of vaccination is the deltoid muscle. The preferred site for infants and young children is the anterolateral aspect of the thigh. Specific guidance regarding site and needle length for intramuscular administration may be found in the ACIP General Recommendations on Immunization (CDC. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices, 2011. MMWR 2011;60[No. RR-2]).

§ The preferred site is over the deltoid muscle. Fluzone Intradermal is administered using the delivery system included with the vaccine.

** Inactivated influenza vaccine, high dose: A 0.5-mL dose contains 60 µg of each vaccine antigen (180 µg total).

†† Inactivated influenza vaccine, intradermal: A 0.1-mL dose contains 9 µg of each vaccine antigen (27 µg total).

§§ The quadrivalent formulation of FluMist has replaced the trivalent formulation for the 2013-2014 season. FluMist is shipped refrigerated and stored in the refrigerator at 35°F-46°F (2°C-8°C) after arrival in the vaccination clinic. The dose is 0.2 mL divided equally between each nostril. Health-care providers should consult the medical record, when available, to identify children aged 2-4 years with asthma or recurrent wheezing that might indicate

asthma. In addition, to identify children who might be at greater risk for asthma and possibly at increased risk for wheezing after receiving LAIV, parents or caregivers of children aged 2-4 years should be asked: "In the past 12 months, has a health-care provider ever told you that your child had wheezing or asthma?" Children whose parents or caregivers answer "yes" to this question and children who have asthma or who had a wheezing episode noted in the medical record within the past 12 months should not receive FluMist.

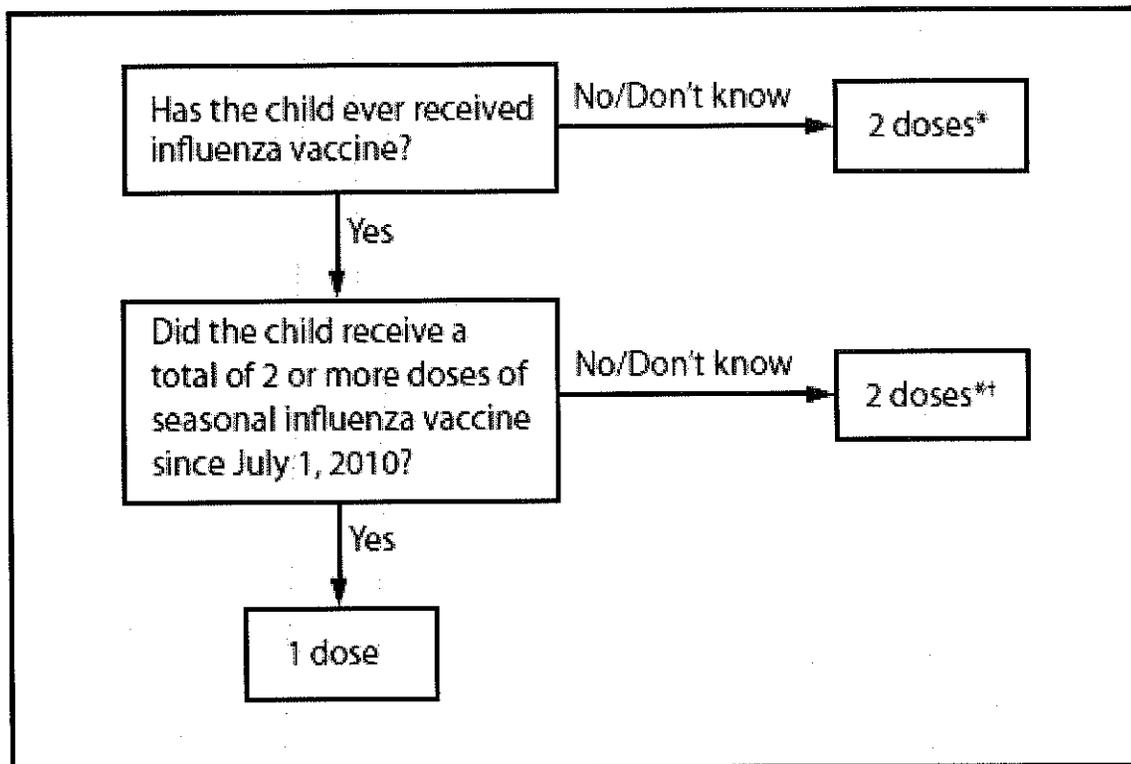
††† Age indication per package insert is ≥ 5 years; however, ACIP recommends that Afluria not be used in children aged 6 months through 8 years because of increased risk for febrile reactions in this age group with CSL's 2010 Southern Hemisphere IIV3. If no other age-appropriate, licensed inactivated seasonal influenza vaccine is available for a child aged 5-8 years who has a medical condition that increases the child's risk for influenza complications, Afluria can be used; however, providers should discuss with the parents or caregivers the benefits and risks of influenza vaccination with Afluria before administering this vaccine. Afluria may be used in persons aged ≥ 9 years.

*** FluMist is indicated for healthy, nonpregnant persons aged 2 through 49 years. Persons who care for severely immunosuppressed persons who require a protective environment should not receive FluMist given the theoretical risk for transmission of the live-attenuated vaccine virus.

§§§ Information not included in package insert. The total egg protein is estimated to be less than 50 femtograms (5×10^{-14} grams) total egg protein (of which a fraction is ovalbumin) per 0.5 mL dose of Flucelvax.

¶¶¶ Available on request from Sanofi Pasteur, telephone 1-800-822-2463 or email MIS.Emails@sanofipasteur.com.

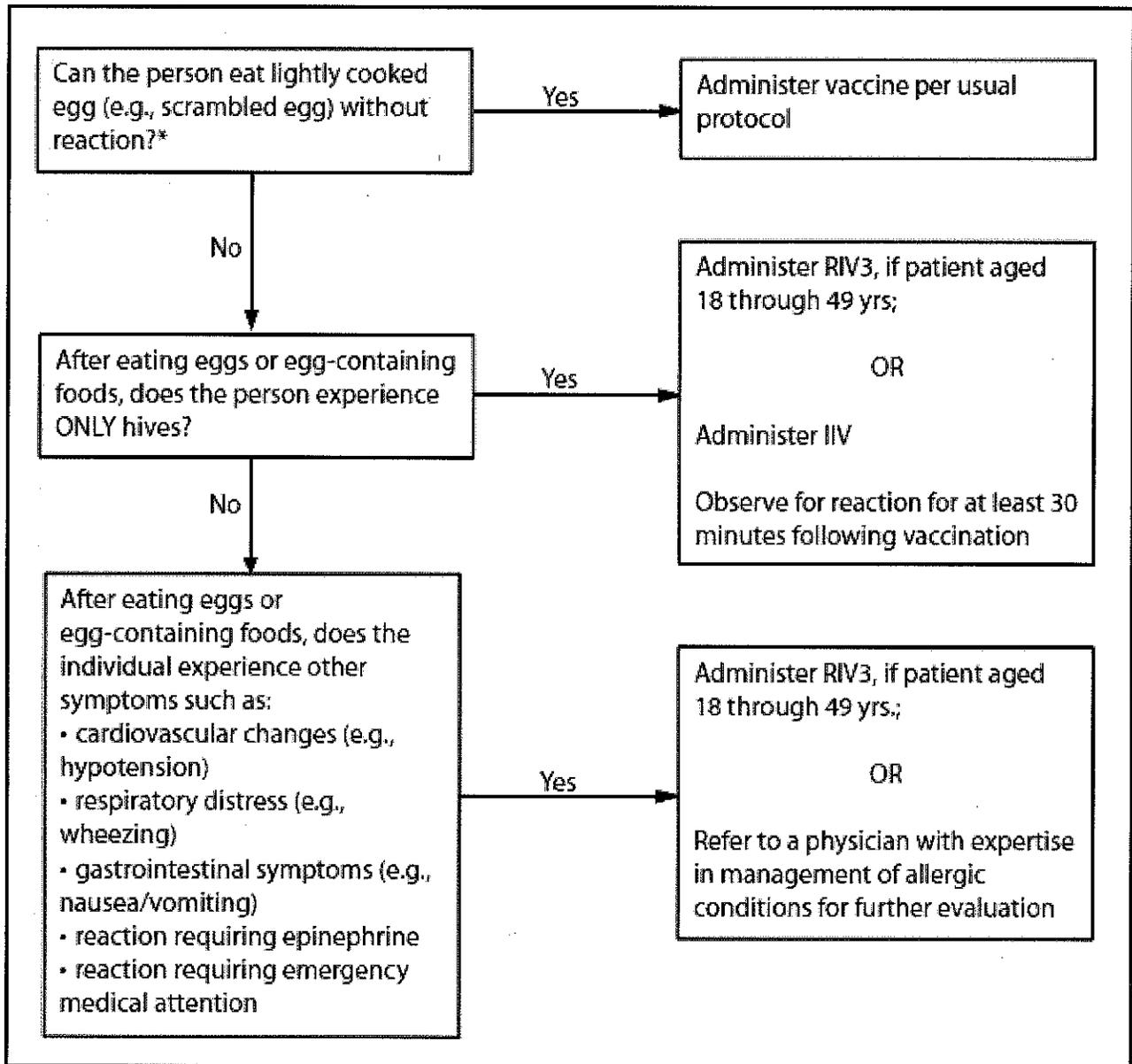
FIGURE 1. Influenza vaccine dosing algorithm for children aged 6 months through 8 years — Advisory Committee on Immunization Practices, United States, 2013-2014 influenza season



* Doses should be administered at least 4 weeks apart.

† For simplicity, this algorithm takes into consideration only doses of seasonal influenza vaccine received since July 1, 2010. As an alternative approach in settings where vaccination history from before July 1, 2010, is available, if a child aged 6 months through 8 years is known to have received at least 2 seasonal influenza vaccines during any previous season, and at least 1 dose of a 2009(H1N1)-containing vaccine (i.e., 2010-2011, 2011-2012 or 2012-2013 seasonal vaccine or the monovalent 2009[H1N1] vaccine), then the child needs only 1 dose for the 2013-2014 season. Using this approach, children aged 6 months through 8 years need only 1 dose of vaccine in 2013-2014 if they have received any of the following: 1) 2 or more doses of seasonal influenza vaccine since July 1, 2010; 2) 2 or more doses of seasonal influenza vaccine before July 1, 2010, and 1 or more doses of monovalent 2009(H1N1) vaccine; or 3) 1 or more doses of seasonal influenza vaccine before July 1, 2010, and 1 or more doses of seasonal influenza vaccine since July 1, 2010. Children in this age group for whom one of these conditions is not met require 2 doses in the 2013-2014 season.

FIGURE 2. Recommendations regarding influenza vaccination of persons who report allergy to eggs — Advisory Committee on Immunization Practices, United States, 2013-2014 influenza season



Abbreviations: IIV = inactivated influenza vaccine; RIV3 = recombinant influenza vaccine, trivalent.

* Persons with egg allergy might tolerate egg in baked products (e.g., bread or cake). Tolerance to egg-containing foods does not exclude the possibility of egg allergy. For persons who have no known history of exposure to egg but who are suspected of being egg-allergic on the basis of previously performed allergy testing, consultation with a physician with expertise in the management of allergic conditions should be obtained prior to vaccination. Alternatively, RIV3 may be administered if the recipient is aged 18 through 49 years.