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Date: September 12, 2012

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 Practices

Jay A. Gold, MD, JD, MPH  
Wisconsin Adult Immunization Coalition

Re: 2012-2013 Recommendations for Use of Seasonal Influenza Vaccines

**Summary of Recommendations**

**The 2012-2013 Advisory Committee on Immunization Practices (ACIP) recommendations include five principal updates:**

1. The composition of the 2012-2013 trivalent influenza vaccine includes the following three influenza virus strains: A/California/7/2009 (H1N1)-like, A/Victoria/361/2011 (H3N2)-like, and B/Wisconsin/1/2010-like (Yamagata lineage) antigens. The trivalent inactivated vaccine (TIV) and live-attenuated influenza vaccine (LAIV) will contain these three antigens. Note that the influenza A(H3N2) and B antigens differ from the respective 2010-11 and 2011-12 seasonal vaccine antigens. The influenza A(H1N1) antigen has not changed.

2. Children aged 6 months through 8 years who last received seasonal (trivalent) influenza vaccine before the 2010-11 season but did not receive a vaccine containing A/2009(H1N1) antigen [either seasonal vaccine since July 2010 or monovalent 2009(H1N1) vaccine] will not have received this antigen. These children are recommended to receive two doses this season, even if two doses of seasonal influenza vaccine were received before the 2010-11 season [see Figure 1.]

3. The ACIP does not recommend the U.S.-licensed CSL Biotherapies' TIV, Afluria, for children aged <9 years because of reports of an increased risk of fever and febrile seizures among young children in Australia associated with receipt of an influenza vaccine produced by CSL Biotherapies that was formulated for use during 2010 in the Southern Hemisphere.

Surveillance for U.S.-licensed influenza vaccines during the 2010-11 season detected safety signals for febrile seizures among young children after TIV administration. Further assessment determined that the increased risk occurred on the day of vaccination and the day after vaccination (the 0-1 day risk window)

among children aged 6 months through 4 years. The risk was greater when children received concomitant 13-valent pneumococcal conjugate vaccine (PCV-13) and peaked at approximately age 16 months.

Following evaluation of data regarding febrile seizures during the 2010-11 and 2011-12 influenza seasons and the consideration of the benefits and risks of vaccination, no policy change was recommended for use of TIV or PCV13 during the 2011-12 influenza season and there is no change in the recommended use of these two vaccines during the 2012-13 influenza season.

4. Egg allergic persons who have experienced only hives after exposure to egg should receive influenza vaccine with the following additional safety measures: TIV rather than LAIV should be used, vaccine should be administered by a health care provider who is familiar with the potential manifestations of egg allergy, and vaccine recipients should be observed for at least 30 minutes for signs of a reaction after administration of each vaccine dose [see Figure 2.]

Persons who have had severe reactions to egg including angioedema, respiratory distress, lightheadedness, or recurrent vomiting, or who have required emergency medical intervention are more likely to experience serious side effects to egg proteins. These persons should be referred to a physician with expertise in management of allergic conditions for further risk assessment.

5. During February 2012, the Food and Drug Administration (FDA) approved a new seasonal quadrivalent LAIV, FluMist Quadrivalent (MedImmune). This vaccine currently is not anticipated to be available until the 2013-14 influenza season, at which time it is expected to replace the currently available seasonal trivalent FluMist formulation. Inactivated quadrivalent influenza vaccines currently are in development.



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### **Full Recommendations**

The 2012-2013 Advisory Committee on Immunization Practices (ACIP) recommendations for the prevention and control of seasonal influenza with vaccines were formally issued on August 17, 2012. This document can be downloaded from the MMWR website at [www.cdc.gov/mmwr](http://www.cdc.gov/mmwr). 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](http://www.cdc.gov/flu) as needed. The 2012-2013 Vaccine Information Statements (VIS) for Influenza are available at [www.cdc.gov/vaccines/pubs/vis/default.htm](http://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 (TIV) formulated for the 2012-2013 influenza season. The name of the company and vaccine/s that they produce are: Sanofi Pasteur (Fluzone<sup>®</sup>, Fluzone High-Dose<sup>®</sup>, and Fluzone Intradermal<sup>®</sup>), Novartis Vaccines (Agriflu<sup>®</sup> and Fluvirin<sup>®</sup>), GlaxoSmithKline (Fluarix<sup>™</sup>), CSL Biotherapies (Afluria<sup>®</sup>), and ID Biomedical Corporation of Quebec (FluLaval<sup>™</sup>). One company, MedImmune, Inc., is manufacturing the live, attenuated seasonal influenza vaccine (LAIV) FluMist<sup>™</sup> for the U.S. market (Table).

For the 2012-2013 influenza season we recommend that providers begin offering vaccination as soon as vaccine is available. Vaccination of all persons aged  $\geq 6$  months continues to be recommended. It is also important to continue to offer seasonal influenza vaccine throughout the influenza season and schedule immunization clinics throughout the influenza season to include December and later.

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 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 these local coalitions to help coordinate redistribution and use of influenza vaccine.

**TABLE. Influenza vaccine information, by age group — United States, 2012-13 influenza season\***

Vaccine	Trade name	Manufacturer	Presentation	Mercury content ( $\mu\text{g}$ Hg/0.5 mL dose)	Ovalbumin content ( $\mu\text{g}$ /0.5 mL dose) <sup>†</sup>	Age group	No. of doses	Route
TIV	Fluzone	Sanofi Pasteur	0.25 mL prefilled syringe	0.0	—§	6-35 mos	1 or 2¶	IM**
			0.5 mL prefilled syringe	0.0	—§	≥36 mos	1 or 2¶	IM**
			0.5 mL vial	0.0	—§	≥36 mos	1 or 2¶	IM**
			5.0 mL multidose vial	25.0	—§	≥6 mos	1 or 2¶	IM**
TIV	Agriflu	Novartis Vaccines	0.5 mL prefilled syringe	0	<0.4	≥18 yrs	1	IM**
TIV	Fluvirin	Novartis Vaccines	0.5 mL prefilled syringe	≤1	≤1	≥4 yrs	1 or 2¶	IM**
			5.0 mL multidose vial	25.0	≤1			
TIV	Fluarix	GlaxoSmithKline	0.5 mL prefilled syringe	0	≤0.05	≥3 yrs	1 or 2¶	IM**
TIV	FluLaval	ID Biomedical Corporation of Quebec (distributed by GlaxoSmithKline)	5.0 mL multidose vial	<25.0	≤0.3	≥18 yrs	1	IM**
TIV	Afluria	CSL Biotherapies (distributed by Merck)	0.5 mL prefilled syringe	0.0	≤1	≥9 yrs††	1	IM**
			5.0 mL multidose vial	24.5	≤1			
TIV High-Dose§§	Fluzone High-Dose	Sanofi Pasteur	0.5 mL prefilled syringe	0.0	—§	≥65 yrs	1	IM**

TIV Intradermal¶¶	Fluzone Intradermal	Sanofi Pasteur	0.1 mL prefilled microinjection system	0.0 (per 0.1 mL)	—§	18-64 yrs	1	ID
LAIV	FluMist***	MedImmune	0.2 mL prefilled intranasal sprayer	0.0 (per 0.2 mL)	<0.24 (per 0.2 mL)†††	2-49 yrs§§§	1 or 2¶	IN

**Abbreviations:** TIV = trivalent inactivated vaccine; LAIV = live-attenuated influenza vaccine; IM = intramuscular; ID = intradermal; IN = intranasal.

\* Vaccination providers should check Food and Drug Administration-approved prescribing information for 2012-13 influenza vaccines for the most updated information.

† Data on maximum ovalbumin content is supplied in package inserts of certain vaccines. Persons with a history of mild allergy to egg (specifically, those who experience only hives) should receive TIV with additional precautions (Figure 2).

§ Information is not included in package insert but is available upon request from the manufacturer, Sanofi Pasteur, by contacting 1-800-822-2463 or [mis.emails@sanofipasteur.com](mailto:mis.emails@sanofipasteur.com).

¶ Figure 1 describes two approaches for determining the number of doses needed for children aged 6 months through 8 years.

\*\* 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.

†† Age indication per package insert is  $\geq 5$  years; however, the Advisory Committee on Immunization Practices recommends Afluria not be used in children aged 6 months through 8 years because of increased reports of febrile reactions in this age group. 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  $\geq 9$  years.

§§ TIV high-dose: A 0.5-mL dose contains 60  $\mu\text{g}$  of each vaccine antigen (180  $\mu\text{g}$  total).

¶¶ TIV intradermal: a 0.1-mL dose contains 9  $\mu\text{g}$  of each vaccine antigen (27  $\mu\text{g}$  total).

\*\*\* 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.

††† Insufficient data available for use of LAIV in egg-allergic persons.

§§§ 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.

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**Additional Influenza Vaccination Issues and Recommendations:**

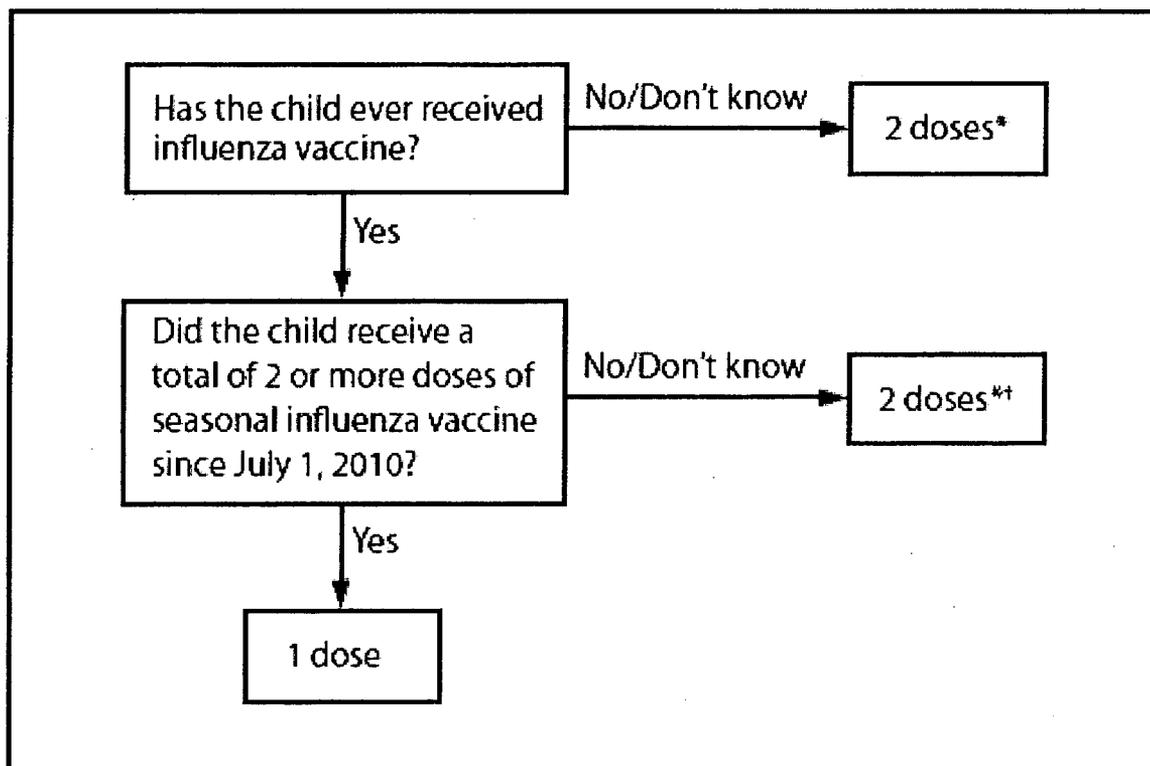
1. Either TIV or LAIV can be used when vaccinating healthy, nonpregnant persons aged 2-49 years.
2. Vaccination of children younger than age 9 years who are receiving seasonal influenza vaccine for the first time can begin as soon as vaccine becomes available. This practice increases the opportunity for both doses to be administered during the same influenza season and before the onset of influenza activity.
3. Children aged 6-35 months should only receive a 0.25 mL dose of a split-virus vaccine formulation. Currently only Sanofi Pasteur provides this presentation.
4. Influenza vaccine without thimerosal (as a preservative) will be available in limited supply during the 2012-2013 influenza season. The supply of this vaccine will be increased as manufacturing capabilities are expanded. Elimination of thimerosal in other vaccines has already been achieved and has resulted in substantially lowered cumulative exposure to thimerosal. The ACIP states that persons for whom inactivated vaccine is recommended may receive any age and risk factor appropriate vaccine preparation, depending on availability.
5. The first and second doses of vaccine do not have to match; TIV or LAIV can be used to complete the two-dose requirement. Doses should be separated by at least 4 weeks.

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.

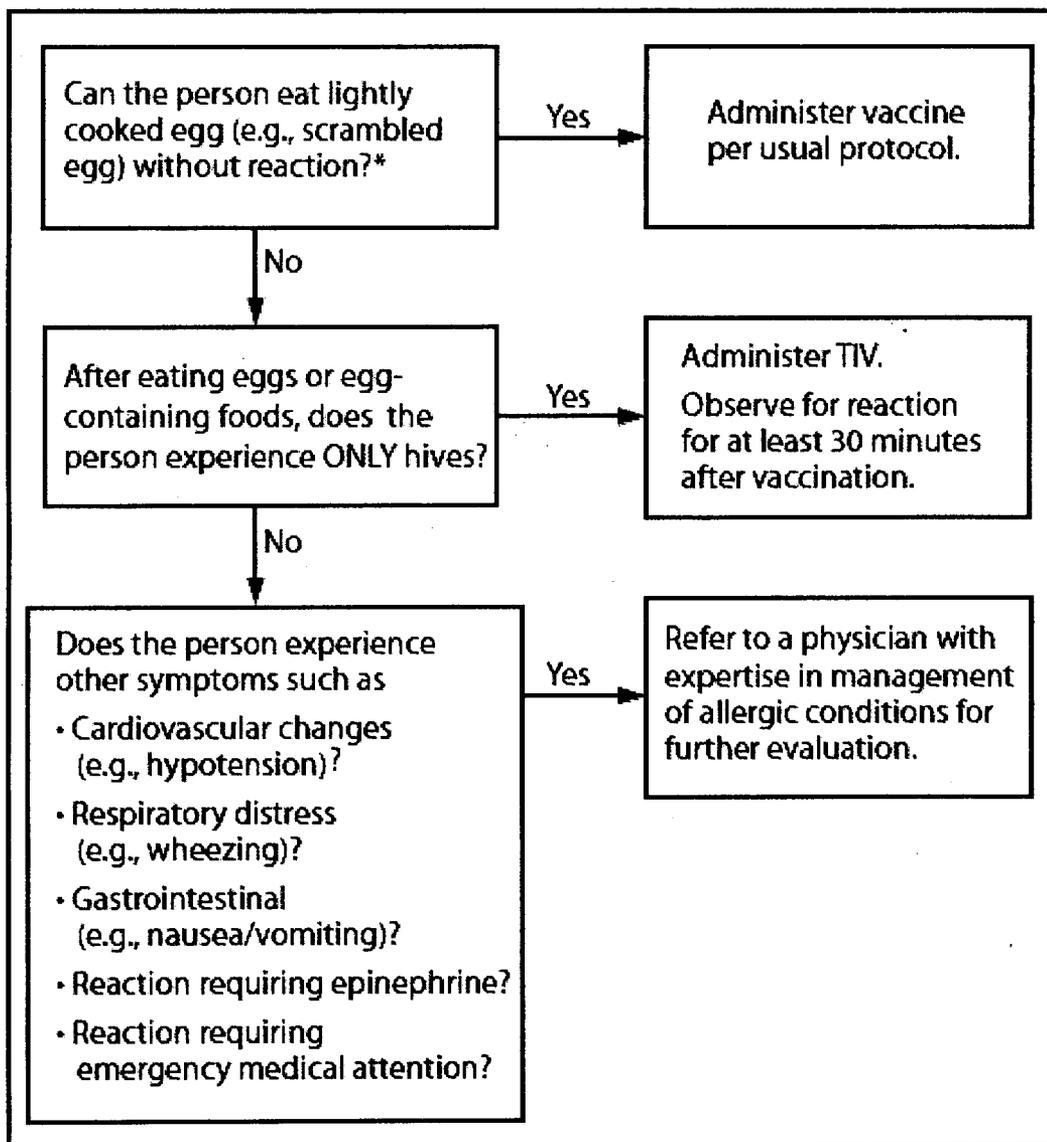
**FIGURE 1. Influenza vaccine dosing algorithm for children aged 6 months through 8 years — Advisory Committee on Immunization Practices, United States, 2012-13 influenza season**



\* 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., either 2010–11 or 2011–12 seasonal vaccine or the monovalent 2009[H1N1] vaccine), then the child needs only 1 dose for 2012–13. Using this approach, children aged 6 months through 8 years need only 1 dose of vaccine in 2012–13 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 for whom one of these conditions is not met require 2 doses in 2012–2013.

**FIGURE 2. Recommendations regarding influenza vaccination for persons who report allergy to eggs — Advisory Committee on Immunization Practices, United States, 2012-13 influenza season**



Abbreviation: TIV = trivalent inactivated vaccine.

\* 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.