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Date: October 2, 2015

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

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Re: The 2015-2016 Advisory Committee on Immunization Practices (ACIP) recommendations for the prevention and control of seasonal influenza with vaccines

Summary of updates to the ACIP Recommendations

The principal updates to the 2015-2016 Advisory Committee on Immunization Practices (ACIP) recommendations for the prevention and control of seasonal influenza with vaccines are**:**

1. The composition of the 2015-2016 trivalent influenza vaccine includes the following three influenza virus strains: A/California/7/2009 (H1N1)-like virus, A/Switzerland/9715293/2013 (H3N2)-like virus, and B/Phuket/3073/2013-like (Yamagata lineage) virus. Quadrivalent vaccines will include an additional vaccine virus, a B/Brisbane/60/2008-like (Victoria lineage) virus.

2. Because of the change in vaccine composition for the 2015-2016 season, children aged 6 months through 8 years who previously received ≥2 doses of influenza vaccine require only 1 dose for the 2015-2016 season. The two previous doses need not have been administered during the same season or in consecutive seasons.

3. The ACIP has determined that in the absence of data from recent seasons demonstrating consistent greater relative effectiveness of the current quadrivalent formulation of live-attenuated influenza vaccine (LAIV), there is no longer preference for LAIV over inactivated influenza vaccine (IIV).

The full ACIP Recommendations

The 2015-2016 Advisory Committee on Immunization Practices (ACIP) recommendations for the prevention and control of seasonal influenza with vaccines were formally issued on August 7, 2015. This document can be downloaded from the MMWR website at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6430a3.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 2015-2016 Vaccine Information Statements (VIS) for Influenza are available at http://www.cdc.gov/vaccines/hcp/vis/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 for the 2015-2016 season are:

- Quadrivalent inactivated influenza vaccine (IIV4)
  - Sanofi Pasteur (Fluzone® Quadrivalent, Fluzone® Intradermal Quadrivalent), GlaxoSmithKline (Fluarix® Quadrivalent), and ID Biomedical Corporation of Quebec (FluLaval® Quadrivalent)
- Live-attenuated influenza vaccine, quadrivalent (LAIV4)
  - MedImmune, Inc (FluMist™)
- Trivalent inactivated influenza vaccine (IIV3)
  - Sanofi Pasteur (Fluzone® and Fluzone High-Dose®), Novartis Vaccines and Diagnostics (Flucelvax® and Fluvirin®), and bioCSL (Afluria®)
- Recombinant hemagglutinin (HA) vaccine (RIV3)
  - Protein Sciences (FluBlok®), for persons with egg allergy of any severity

During the 2015-2016 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. It is also important to continue to offer seasonal influenza vaccine as long as influenza viruses are circulating and to schedule immunization clinics throughout the influenza season into 2016, because influenza was detected among Wisconsin residents during all but three weeks during 2014. To avoid missed opportunities for vaccination, providers should offer vaccination during routine health care visits and hospitalizations when vaccine is available.

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 2015-2016 ACIP Recommendations include three principal updates:

1. The composition of the 2015-2016 trivalent influenza vaccine includes the following three influenza virus strains: A/California/7/2009 (H1N1)-like virus, A/Switzerland/9715293/2013 (H3N2)-like virus, and B/Phuket/3073/2013-like (Yamagata lineage) virus. Quadrivalent vaccines will include an additional vaccine virus, a B/Brisbane/60/2008-like (Victoria lineage) virus.

2. Because of the change in vaccine composition for the 2015-2016 season, children aged 6 months through 8 years who previously received ≥2 doses of influenza vaccine require only 1 dose for the 2015-2016 season. The two previous doses need not have been administered during the same season or in consecutive seasons.

3. The ACIP has determined that in the absence of data from recent seasons demonstrating consistent greater relative effectiveness of the current quadrivalent formulation of live-attenuated influenza vaccine (LAIV), there is no longer preference for LAIV over inactivated influenza vaccine (IIV).

Influenza vaccination of children aged 6 months through 8 years

1. All children aged 6 months through 8 years who are recommended to receive 2 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. The first and second doses of vaccine do not have to match; IIV or LAIV can be used to complete the two-dose requirement.

2. If a child receives IIV4 or LAIV4 for one of their two doses but not for both doses (i.e., received IIV3 for one dose), 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 receiving IIV4 should only receive a 0.25 mL dose of a split-virus vaccine formulation. Currently only Sanofi Pasteur provides this presentation.

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 (1).

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.

Influenza vaccination of persons with a history of egg allergy

1. The ACIP has recommended that persons with egg allergy who have experienced 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 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, IIV should be administered by a physician with experience in the recognition and management of severe allergic conditions.

3. Regardless of allergy history, all vaccines should be administered to patients with a history of egg allergy in settings in which personnel and equipment for rapid recognition and treatment of anaphylaxis are available.

4. Persons who are able to eat lightly cooked egg without reaction are unlikely to be allergic. Tolerance to egg-containing foods does not exclude the possibility of egg allergy. Egg allergy can be confirmed by a consistent medical history of adverse reactions to eggs and egg-containing foods, plus skin and/or blood testing for immunoglobulin E directed against egg proteins.

5. For persons with 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 before vaccination. Alternatively, RIV3 may be administered if the recipient is aged ≥18 years.

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	Rhinelander 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 vaccines, by formulation – United States, 2015-2016 influenza season*

Trade name	Manufacturer	Presentation	Mercury (from thimerosal) (μg/0.5 mL)	Ovalbumin (μg/0.5mL)	Age indications	Route	Latex
Inactivated influenza vaccine, quadrivalent (IIV4), standard dose *Contraindications*: Severe allergic reaction to any vaccine component, including egg protein, or after previous dose of any influenza vaccine.* *Precautions*: Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.*							
Fluarix Quadrivalent	GlaxoSmithKline	0.5 mL single-dose prefilled syringe	—	≤0.05	≥3 yrs	IM†	No
FluLaval Quadrivalent	ID Biomedical Corp. of Quebec (distributed by GlaxoSmithKline)	5.0 mL multi-dose vial	<25	≤0.3	≥3 yrs	IM†	No
Fluzone Quadrivalent	Sanofi Pasteur	0.25 mL single-dose prefilled syringe	—	§	6–35 mos	IM†	No
		0.5 mL single-dose prefilled syringe	—	§	≥36 mos	IM†	No
		0.5 mL single-dose vial	—	§	≥36 mos	IM†	No
		5.0 mL multi-dose vial	25	§	≥6 mos	IM†	No
Fluzone Intradermal Quadrivalent¶	Sanofi Pasteur	0.1 mL single-dose prefilled microinjection system	—	§	18-64 yrs	ID**	No
Inactivated influenza vaccine, trivalent (IIV3), standard dose *Contraindications*: Severe allergic reaction to any vaccine component, including egg protein, or after previous dose of any influenza vaccine.* *Precautions*: Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.*							
Afluria	bioCSL	0.5 mL single-dose prefilled syringe	—	<1	≥9 yrs††	IM†	
		5.0 mL multi-dose vial	24.5	<1	≥9 yrs†† via needle;18-64 yrs via jet injector	IM†	
Fluvirin	Novartis Vaccines and Diagnostics	0.5 mL single-dose prefilled syringe	≤1	≤1	≥4 yrs	IM†	Yes§§
		5.0 mL multi-dose vial	25	≤1	≥4 yrs	IM†	No

Fluzone	Sanofi Pasteur	5.0 mL multi-dose vial	25	§	≥6 mos	IM†	No
Inactivated influenza vaccine, cell culture-based (ccIIV3), standard dose *Contraindications*: Severe allergic reaction to any vaccine component, including egg protein, or after previous dose of any influenza vaccine.* *Precautions*: Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.*							
Flucelvax	Novartis Vaccines and Diagnostics	0.5 mL single-dose prefilled syringe	—	¶¶	≥18 yrs	IM†	Yes§§
Inactivated influenza vaccine, trivalent (IIV3), high dose *Contraindications*: Severe allergic reaction to any vaccine component, including egg protein, or after previous dose of any influenza vaccine.* *Precautions*: Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.*							
Fluzone High-Dose***	Sanofi Pasteur	0.5 mL single-dose prefilled syringe	—	§	≥65 yrs	IM†	No
Recombinant influenza vaccine, trivalent (RIV3) *Contraindications*: Severe allergic reaction to any vaccine component.* *Precautions*: Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.*							
FluBlok	Protein Sciences	0.5 mL single-dose vial	—	0	≥18 yrs	IM†	No
Live attenuated influenza vaccine, quadrivalent (LAIV4) *Contraindications*: Severe allergic reaction to any vaccine component, including egg protein, or after previous dose of any influenza vaccine.* *Concomitant use of aspirin or aspirin-containing medications in children and adolescents.* *In addition, ACIP recommends LAIV4 not be used for pregnant women, immunosuppressed persons, persons with egg allergy, and children aged 2–4 years who have asthma who have had a wheezing episode noted in the medical record within the past 12 months, or for whom parents report that a health care provider stated that they had wheezing or asthma within the last 12 months.* *LAIV should not be administered to persons who have taken influenza antiviral medications within the previous 48 hours.* *Persons who care for severely immunosuppressed persons who require a protective environment should not receive LAIV4, or should avoid contact with such persons for 7 days after receipt.* *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 and older.* *Medical conditions which might predispose to higher risk for complications attributable to influenza.*							
FluMist Quadrivalent†††	MedImmune	0.2 mL single-dose prefilled intranasal sprayer	—	<0.24 (per 0.2 mL)	2–49 yrs	IN	No

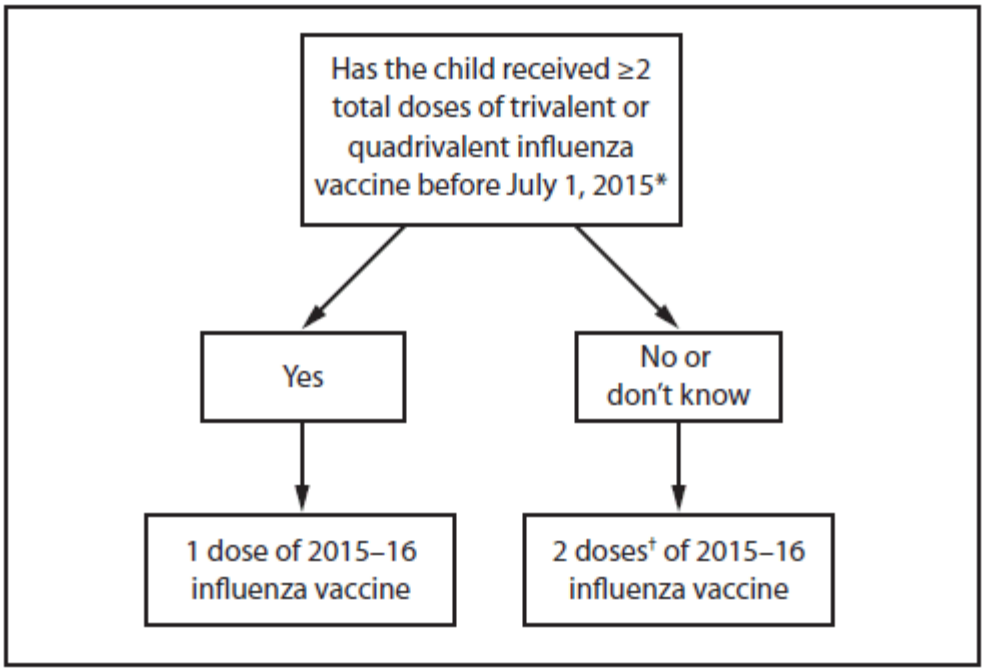
Abbreviations: ACIP = Advisory Committee on Immunization Practices; ID = intradermal; IM = intramuscular; IN = intranasal.

* Immunization providers should check Food and Drug Administration–approved prescribing information for 2015–2016 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 http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm.

† 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. Specific guidance regarding site and needle length for intramuscular administration may be found in ACIP General Recommendations on Immunization, available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm.

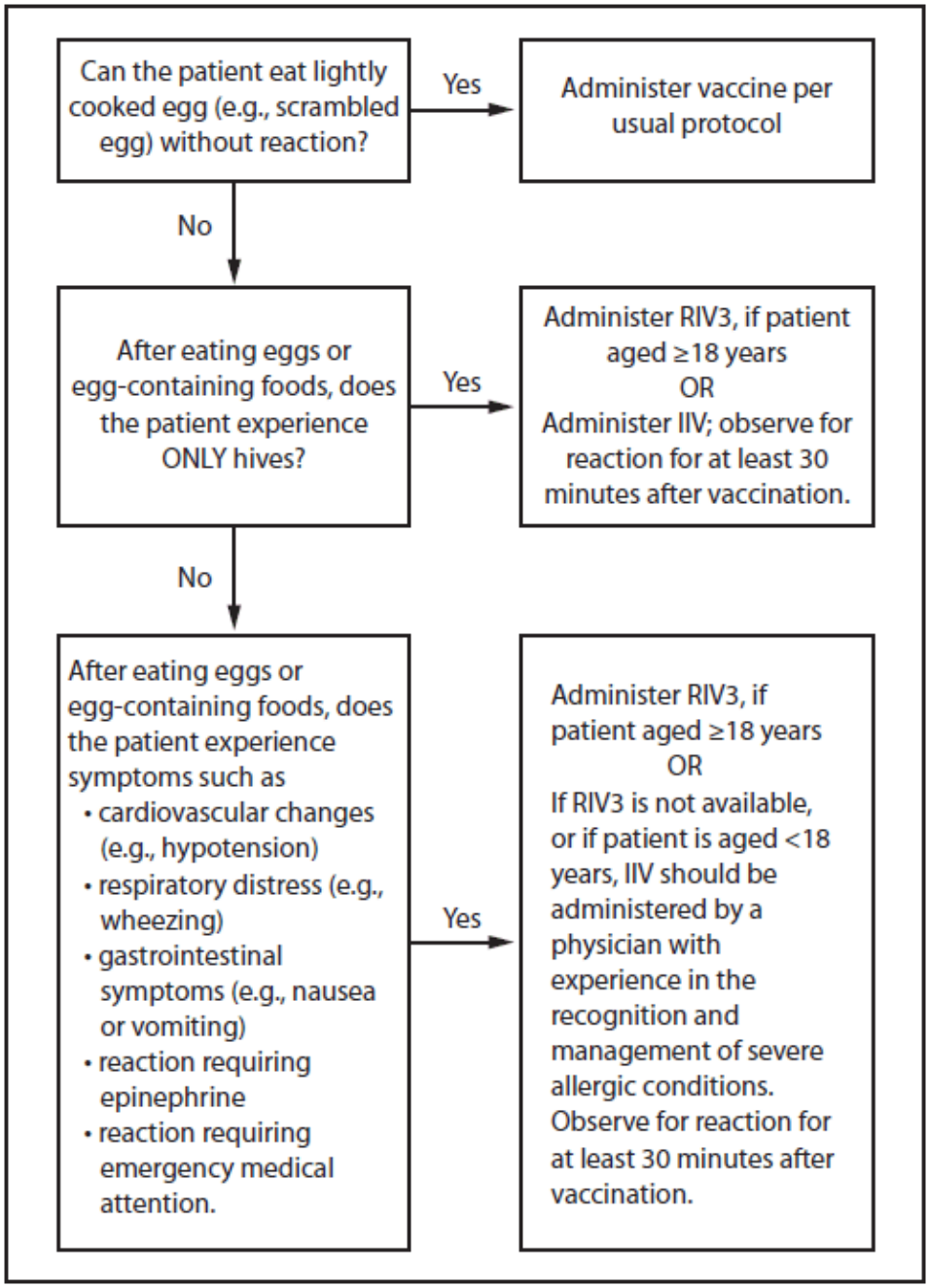
§ Available upon request from Sanofi Pasteur (telephone: 1-800-822-2463; e-mail: MIS.Emails@sanofipasteur.com).
¶ Quadrivalent inactivated influenza vaccine, intradermal: a 0.1-mL dose contains 9 μg of each vaccine antigen (36 μg total)
** The preferred injection site is over the deltoid muscle. Fluzone Intradermal Quadrivalent is administered using the delivery system included with the vaccine.
†† Age indication per package insert is ≥5 years; however, ACIP recommends Afluria not be used in children aged 6 months through 8 years because of increased risk of febrile reactions noted in this age group with bioCSL's 2010 Southern Hemisphere IIV3. If no other age-appropriate, licensed inactivated seasonal influenza vaccine is available for a child aged 5 through 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.
§§ Syringe tip cap may contain natural rubber latex.
¶¶ Information not included in package insert. Estimated to contain <50 femtograms (5x10-8 μg) of total egg protein (of which ovalbumin is a fraction) per 0.5 mL dose of Flucelvax.
*** Trivalent inactivated vaccine, high-dose: A 0.5-mL dose contains 60 μg of each vaccine antigen (180 μg 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 through 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 through 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.

FIGURE 1. Influenza vaccine dosing algorithm for children aged 6 months through 8 years — Advisory Committee on Immunization Practices, United States, 2015-2016 influenza season



*The two doses need not have been received during the same season or consecutive seasons.
†Doses should be administered ≥4 weeks apart.

FIGURE 2. Recommendations regarding influenza vaccination of persons who report allergy to eggs*† — Advisory Committee on Immunization Practices, United States, 2015-2016 influenza season



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

*Persons with egg allergy may tolerate egg in baked products (e.g., bread or cake). Tolerance to egg-containing foods does not exclude the possibility of egg allergy (Erlewyn-Lajeunesse et al., Recommendations for the administration of influenza vaccine in children allergic to egg. BMJ 2009;339:b3680).

†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 years.