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Date: October 12, 2016

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

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

James H. Conway, MD, FAAP 
Wisconsin Chapter of the American Academy of Pediatrics

Jonathan L. Temte, MD, PhD 
Chair, Wisconsin Council on Immunization Practices

Re: The 2016-2017 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 2016-2017 ACIP recommendations for the prevention and control of seasonal influenza with vaccines are:

1. Because of the low vaccine effectiveness against influenza A(H1N1)pdm09 in the U. S. during the 2013–2014 and 2015–2016 seasons, for the 2016–2017 season, the ACIP made the interim recommendation that LAIV4 should not be used. Because LAIV4 is still a licensed vaccine that might be available and that some providers might elect to use, for informational purposes, reference is made to previous recommendations for its use.
2. The 2016–2017 U.S. trivalent influenza vaccines will contain an A/California/7/2009 (H1N1)–like virus, an A/Hong Kong/4801/2014 (H3N2)–like virus and a B/Brisbane/60/2008–like virus (Victoria lineage). Quadrivalent vaccines will include an additional vaccine virus strain, a B/Phuket/3073/2013–like virus (Yamagata lineage).
3. Recent new vaccine licensures include:
 - An MF59-adjuvanted trivalent inactivated influenza vaccine (aIIV3), Flud (Seqirus, Holly Springs, North Carolina), was licensed by FDA during November 2015 for use among persons aged ≥ 65 years. Regulatory information is available at <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm473989.htm>. aIIV3 is an acceptable alternative to other vaccines licensed for use among persons in this age group. The ACIP and CDC do not express a preference for use of any particular vaccine product.
 - A quadrivalent formulation of Flucelvax (cell culture-based inactivated influenza vaccine [ccIIV4], Seqirus, Holly Springs, North Carolina) was licensed by FDA during May 2016, for use among persons aged ≥ 4 years. Regulatory information is available at: <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm502844.htm>. The ccIIV4 is an acceptable alternative to other vaccines licensed for persons in this age group. No preference is expressed for use of any particular vaccine product.

4. Recommendations for influenza vaccination of persons with an egg allergy have been modified, including:
 - Removal of the recommendation that egg-allergic recipients should be observed for 30 minutes post-vaccination for signs and symptoms of an allergic reaction. Providers should consider observing all patients for 15 minutes after vaccination to decrease the risk for injury should they experience syncope, per the ACIP General Recommendations on Immunization (1).
 - A recommendation that persons with a history of severe allergic reaction to egg (i.e., any sign or symptom other than hives) should be vaccinated in an inpatient or outpatient medical setting (including but not necessarily limited to hospitals, clinics, health departments, and physician offices), under the supervision of a health care provider who is able to recognize and manage severe allergic conditions.

The full ACIP Recommendations

The 2016-2017 ACIP recommendations for the prevention and control of seasonal influenza with vaccines were formally issued on August 26, 2016. This document can be downloaded from the MMWR website at: <http://www.cdc.gov/mmwr/volumes/65/rr/rr6505a1.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 2016-2017 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 2016-2017 season are (Table 1):

- Quadrivalent inactivated influenza vaccine (IIV4)
 - Sanofi Pasteur (Fluzone® Quadrivalent, Fluzone® Intradermal Quadrivalent)
 - GlaxoSmithKline (Fluarix® Quadrivalent)
 - ID Biomedical Corporation of Quebec (FluLaval® Quadrivalent)
- Quadrivalent cell-culture based influenza vaccine (ccIIV4): Seqirus (Flucelvax Quadrivalent®)
- Live-attenuated influenza vaccine, quadrivalent (LAIV4): MedImmune, Inc (FluMist™)
- Trivalent inactivated influenza vaccine (IIV3)
 - Sanofi Pasteur (Fluzone High-Dose®)
 - Seqirus (Afluria® and Fluvirin®)
- Adjuvanted inactivated influenza vaccine (aIIV3): Seqirus (Fluad™)
- Recombinant hemagglutinin (HA) vaccine (RIV3): Protein Sciences (FluBlok®), for persons with egg allergy of any severity

During the 2016-2017 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 2017, because influenza was detected among Wisconsin residents during all but four weeks during 2015 (the most current year for which we have complete data). 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 2016-2017 ACIP Recommendations include four principal updates:

1. Because of the low vaccine effectiveness against influenza A(H1N1)pdm09 in the United States during the 2013–2014 and 2015–2016 seasons, for the 2016–2017 season, the ACIP made the interim recommendation that LAIV4 should not be used. Because LAIV4 is still a licensed vaccine that might be available and that some providers might elect to use, for informational purposes, reference is made to previous recommendations for its use (see Table 2 for contraindications and precautions).
2. The 2016–2017 U.S. trivalent influenza vaccines will contain an A/California/7/2009 (H1N1)–like virus, an A/Hong Kong/4801/2014 (H3N2)–like virus and a B/Brisbane/60/2008–like virus (Victoria lineage). Quadrivalent vaccines will include an additional vaccine virus strain, a B/Phuket/3073/2013–like virus (Yamagata lineage).
3. Recent new vaccine licensures include:
 - An MF59-adjuvanted trivalent inactivated influenza vaccine (aIIV3), Fluvad (Seqirus, Holly Springs, North Carolina), was licensed by FDA during November 2015 for use among persons aged ≥ 65 years. Regulatory information is available at <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm473989.htm>. aIIV3 is an acceptable alternative to other vaccines licensed for use among persons in this age group. The ACIP and CDC do not express a preference for use of any particular vaccine product.
 - A quadrivalent formulation of Flucelvax (cell culture-based inactivated influenza vaccine [ccIIV4], Seqirus, Holly Springs, North Carolina) was licensed by FDA during May 2016, for use among persons aged ≥ 4 years. Regulatory information is available at: <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm502844.htm>. The ccIIV4 is an acceptable alternative to other vaccines licensed for persons in this age group. No preference is expressed for use of any particular vaccine product.
4. Recommendations for influenza vaccination of persons with egg allergy have been modified, including:
 - Removal of the recommendation that egg-allergic recipients should be observed for 30 minutes post-vaccination for signs and symptoms of an allergic reaction. Providers should consider observing all patients for 15 minutes after vaccination to decrease the risk for injury should they experience syncope, per the ACIP General Recommendations on Immunization (1).
 - A recommendation that persons with a history of severe allergic reaction to egg (i.e., any sign or symptom other than hives) should be vaccinated in an inpatient or outpatient medical setting (including but not necessarily limited to hospitals, clinics, health departments, and physician offices), under the supervision of a health care provider who is able to recognize and manage severe allergic conditions.

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.
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 (2).
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

For the 2016-2017 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 and recommended influenza vaccine (i.e., any age-appropriate IIV or RIV3) 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 signs or symptoms other than hives, such as angioedema, respiratory distress, lightheadedness, or recurrent emesis; or who required epinephrine or another emergency medical intervention, may similarly receive any licensed and recommended influenza vaccine (i.e., any age-appropriate IIV or RIV3) that is otherwise appropriate for the recipient's age and health status. 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 conditions.
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
Cathy Edwards	Milwaukee Regional Office	414-227-3995
Jacqueline Sills-Ware	Milwaukee Regional Office	414-227-4876
Central Office	Rhineland Regional Office	608-267-9959

Please share this information with other interested parties.

Reference

1. CDC. General recommendations on immunization—recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep 2011;60(No. RR-2).
2. 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 1. Influenza vaccines, by formulation—United States, 2016-2017 influenza season*

Trade name	Manufacturer	Presentation	Mercury (from thimerosal) ($\mu\text{g}/0.5\text{ mL}$)	Age indications	Route	Latex
Inactivated influenza vaccine, quadrivalent (IIV4), standard dose[†]						
Fluarix Quadrivalent	GlaxoSmithKline	0.5 mL single-dose prefilled syringe	NR	≥ 3 yrs	IM [§]	No
FluLaval Quadrivalent	ID Biomedical Corp. of Quebec (distributed by GlaxoSmithKline)	0.5 mL single-dose prefilled syringe	NR	≥ 3 yrs	IM	No
		5.0 mL multi-dose vial	<25	≥ 3 yrs	IM	No
Fluzone Quadrivalent	Sanofi Pasteur	0.25 mL single-dose prefilled syringe	NR	6–35 mos	IM	No
		0.5 mL single-dose prefilled syringe	NR	≥ 36 mos	IM	No
		0.5 mL single-dose vial	NR	≥ 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	NR	18-64 yrs	ID ^{**}	No
Inactivated influenza vaccine, cell culture-based (ccIIV4), standard dose[†]						
Flucelvax Quadrivalent	Seqirus	0.5 mL single-dose prefilled syringe	NR	≥ 4 yrs	IM	No
Inactivated influenza vaccine, trivalent (IIV3), standard dose[†]						
Afluria	Seqirus	0.5 mL single-dose prefilled syringe	NR	≥ 9 yrs ^{††}	IM	No
		5.0 mL multi-dose vial	24.5	≥ 9 yrs ^{††} (needle and syringe) 18-64 yrs (jet injector)	IM	No
Fluvirin	Seqirus	0.5 mL single-dose prefilled syringe	≤ 1	≥ 4 yrs	IM	Yes ^{§§}
		5.0 mL multi-dose vial	25	≥ 4 yrs	IM	No
Adjuvanted inactivated influenza vaccine, trivalent (aIIV3), standard dose[†]						
Fluad	Seqirus	0.5 mL single-dose prefilled syringe	NR	≥ 65 yrs	IM	Yes ^{§§}
Inactivated influenza vaccine, trivalent (IIV3), high dose^{¶¶}						
Fluzone High-Dose	Sanofi Pasteur	0.5 mL single-dose prefilled syringe	NR	≥ 65 yrs	IM	No
Recombinant influenza vaccine, trivalent (RIV3)^{***}						
FluBlok	Protein Sciences	0.5 mL single-dose vial	NR	≥ 18 yrs	IM	No
Live attenuated influenza vaccine, quadrivalent (LAIV4)^{†††}						
FluMist Quadrivalent	MedImmune	0.2 mL single-dose prefilled intranasal sprayer	NR	2–49 yrs	NAS	No

Abbreviations: ACIP = Advisory Committee on Immunization Practices; ID = intradermal; IM = intramuscular; NAS = intranasal; NR = not relevant (does not contain thimerosal).

*Immunization providers should check Food and Drug Administration–approved prescribing information for 2016–17 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>. Availability of specific products and presentations might change and differ from what is described in this table.

†Standard dose intramuscular IIVs contain 15 µg of each vaccine HA antigen (45 µg total for trivalents and 60 µg total for quadrivalents) per 0.5mL dose.

§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 the ACIP General Recommendations on Immunization, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm>.

¶Quadrivalent inactivated influenza vaccine, intradermal: a 0.1-mL dose contains 9 µg of each vaccine HA antigen (36µg 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 that Afluria not be used in children aged 6 months through 8 years because of increased risk for febrile reactions noted in this age group with Seqirus' 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. Afluria is licensed for administration by jet injector for persons aged 18 through 64 years only.

§§Syringe tip cap might contain natural rubber latex.

¶¶High-dose IIV3 contains 60 µg of each vaccine antigen (180 µg total) per 0.5mL dose.

***RIV3 contains 45 µg of each vaccine HA antigen (135 µg total) per 0.5mL dose.

†††ACIP recommends that Flumist (LAIV4) not be used during the 2016–17 season.

TABLE 2. Contraindications and precautions to the use of influenza vaccines—United States, 2016-2017 influenza season*

Vaccine	Contraindications	Precautions
IIV	History of severe allergic reaction to any component of the vaccine [†] or after previous dose of any influenza vaccine	Moderate to severe illness with or without fever History of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine
RIV	History of severe allergic reaction to any component of the vaccine	Moderate to severe illness with or without fever History of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine
LAIV	For the 2016–17 season, ACIP recommends that LAIV not be used. Content below is provided for information.	
	History of severe allergic reaction to any component of the vaccine [†] or after 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 have immunosuppression (including immunosuppression caused by medications or by HIV) Close contacts and caregivers of severely immunosuppressed persons who require a protected environment Pregnancy Receipt of influenza antiviral medication within the previous 48 hours	Moderate to severe 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; IIV = Inactivated Influenza Vaccine; LAIV = Live-Attenuated Influenza Vaccine; RIV = Recombinant Influenza Vaccine.

* Immunization providers should check Food and Drug Administration–approved prescribing information for 2016–17 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>.

† History of severe allergic reaction (e.g., anaphylaxis) to egg is a labeled contraindication to the use of IIV and LAIV. However, ACIP recommends that any licensed, recommended, and appropriate IIV or RIV may be administered to persons with egg allergy of any severity (see Influenza Vaccination of Persons with a History of Egg Allergy).

FIGURE 1. Influenza vaccine dosing algorithm for children aged 6 months through 8 years – Advisory Committee on Immunization Practices, United States, 2016-2017 influenza season

