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Department of Health Services

Date: October 1, 2018

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

From: 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

James M. Vergeront, MD, Acting Chief Medical Officer and
State Epidemiologist for Communicable Diseases

Re: The 2018-2019 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 2018-2019 ACIP recommendations for the prevention and control of seasonal influenza with vaccines are**:**

1. 2018-2019 U.S. trivalent influenza vaccines will contain an A/Michigan/45/2015 (H1N1)pdm09-like virus, an A/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus and a B/Colorado/06/2017-like virus (Victoria lineage). Quadrivalent vaccines will include an additional vaccine virus strain, a B/Phuket/3073/2013-like virus (Yamagata lineage). This represents a change in the influenza A(H1N1)pdm09 virus component from the previous season.
2. Following two seasons (2016-2017 and 2017-2018) during which ACIP recommended that quadrivalent live attenuated influenza vaccine (LAIV4) not be used, ACIP voted in February 2018 to recommend that for the 2018-2019 season, vaccination providers may choose to administer any licensed, age-appropriate influenza vaccine (inactivated influenza vaccine [IIV], quadrivalent recombinant influenza vaccine [RIV4], or LAIV4). LAIV4 is an option for those for whom it is appropriate.
3. Persons with a history of egg allergy of any severity may receive any licensed, recommended, and age-appropriate influenza vaccine (IIV, RIV4, or LAIV4). IIV and RIV4 have been previously recommended. Use of LAIV4 for persons with egg allergy was approved by ACIP in February 2016.
4. Recent regulatory actions include the following:
   - In August 2017, FDA approved an expanded age indication for Afluria Quadrivalent (IIV4). Previously licensed for persons aged ≥18 years, Afluria Quadrivalent is now licensed for ages ≥5 years.
   - In January 2018, FDA approved an expanded age indication for Fluarix Quadrivalent (IIV4). Previously licensed for persons aged ≥3 years, Fluarix Quadrivalent is now licensed for persons aged ≥6 months. Children aged 6 through 35 months may receive Fluarix Quadrivalent at the same 0.5 mL per dose as is used for older children and adults.

The full ACIP Recommendations

The 2018-2019 ACIP recommendations for the prevention and control of seasonal influenza with vaccines were formally issued on August 24, 2018. This document can be downloaded from the MMWR website at: https://www.cdc.gov/mmwr/volumes/67/rr/rr6703a1.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 2018-2019 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 during the 2018-2019 season are (Table 1):

- Quadrivalent inactivated influenza vaccine (IIV4)
  - Sanofi Pasteur (Fluzone® Quadrivalent)
  - GlaxoSmithKline (Fluarix® Quadrivalent)
  - ID Biomedical Corporation of Quebec (FluLaval® Quadrivalent)
  - Seqirus (Afluria®)
- Quadrivalent cell-culture based influenza vaccine (ccIIV4): Seqirus (Flucelvax Quadrivalent®)
- Live-attenuated influenza vaccine, quadrivalent (LAIV4): AstraZeneca (FluMist™)
- Trivalent inactivated influenza vaccine (IIV3)
  - Sanofi Pasteur (Fluzone High-Dose®)
  - Seqirus (Afluria®)
- Adjuvanted inactivated influenza vaccine, trivalent (aIIV3): Seqirus (Fluad™)
- Recombinant hemagglutinin (HA) influenza vaccine (RIV4): Sanofi Pasteur (FluBlok® Quadrivalent), for persons with egg allergy of any severity

During the 2018-2019 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 2019, because influenza was detected among Wisconsin residents during all 52 weeks during 2017 (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 2018-2019 ACIP Recommendations include four principal updates:

1. 2018-2019 U.S. trivalent influenza vaccines will contain an A/Michigan/45/2015 (H1N1)pdm09-like virus, an A/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus and a B/Colorado/06/2017-like virus (Victoria lineage). Quadrivalent vaccines will include an additional vaccine virus strain, a B/Phuket/3073/2013-like virus (Yamagata lineage). This represents a change in the influenza A(H1N1)pdm09 virus component from the previous season.
2. Following two seasons (2016-2017 and 2017-2018) during which ACIP recommended that LAIV4 not be used, ACIP voted in February 2018 to recommend that for the 2018-2019 season, vaccination providers may choose to administer any licensed, age-appropriate influenza vaccine (IIV, RIV4, or LAIV4). LAIV4 is an option for those for whom it is appropriate.
3. Persons with a history of egg allergy of any severity may receive any licensed, recommended, and age-appropriate influenza vaccine (IIV, RIV4, or LAIV4). IIV and RIV4 have been previously recommended. Use of LAIV4 for persons with egg allergy was approved by ACIP in February 2016.
4. Recent regulatory actions include the following:
    - In August 2017, FDA approved an expanded age indication for Afluria Quadrivalent (IIV4). Previously licensed for persons aged ≥18 years, Afluria Quadrivalent is now licensed for ages ≥5 years.
    - In January 2018, FDA approved an expanded age indication for Fluarix Quadrivalent (IIV4). Previously licensed for persons aged ≥3 years, Fluarix Quadrivalent is now licensed for persons aged ≥6 months. Children aged 6 through 35 months may receive Fluarix Quadrivalent at the same 0.5 mL per dose as is used for older children and adults.

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.

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 2018-2019 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 health status may be used.
2. Persons who report having had reactions to egg involving 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, recommended and age-appropriate influenza vaccine (i.e., any IIV, RIV4 or LAIV4) that is otherwise appropriate for the recipient's 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 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

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.

3. Tapia MD, Sow SO, Tamboura B, et al. Maternal immunisation with trivalent inactivated influenza vaccine for prevention of influenza in infants in Mali: a prospective, active-controlled, observer-blind, randomised phase 4 trial. Lancet Infect Dis. 2016;16(9):1026-1035.

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, 2018-2019 influenza season*

Trade name	Manufacturer	Presentation	Mercury (from thimerosal) (μg/0.5 mL)	Age indications	Route	Latex
Inactivated influenza vaccine, quadrivalent (IIV4), standard dose†						
Afluria Quadrivalent	Seqirus	0.5 mL prefilled syringe	No	≥5 yrs	IM†	No
		5.0 mL multi-dose vial	Yes (24.5)	≥5 yrs (needle/ syringe) 18-64 yrs (jet injector)	IM†	No
Fluarix Quadrivalent	GlaxoSmithKline	0.5 mL prefilled syringe	No	≥6 mos	IM†	No
FluLaval Quadrivalent	ID Biomedical Corp. of Quebec	0.5 mL prefilled syringe	No	≥6 mos	IM†	No
		5.0 mL multi-dose vial	Yes (<25)	≥6 mos	IM†	No
Fluzone Quadrivalent	Sanofi Pasteur	0.25 mL prefilled syringe	No	6–35 mos	IM†	No
		0.5 mL prefilled syringe	No	≥3 yrs	IM†	No
		0.5 mL single-dose vial	No	≥3 yrs	IM†	No
		5.0 mL multi-dose vial	Yes (25)	≥6 mos	IM†	No
Inactivated influenza vaccine, cell culture-based (ccIIV4), standard dose†						
Flucelvax Quadrivalent	Seqirus	0.5 mL prefilled syringe	No	≥4 yrs	IM†	No
		5.0 mL multi-dose vial	Yes (25)	≥4 yrs	IM†	No
Inactivated influenza vaccine, trivalent (IIV3), standard dose†						
Afluria	Seqirus	0.5 mL prefilled syringe	No	≥5 yrs	IM†	No
		5.0 mL multi-dose vial	Yes (24.5)	≥5 yrs (needle/ syringe) 18-64 yrs (jet injector)	IM†	No
Adjuvanted inactivated influenza vaccine, trivalent (aIIV3), standard dose†						
Fluad	Seqirus	0.5 mL prefilled syringe	No	≥65 yrs	IM†	No
Inactivated influenza vaccine, trivalent (IIV3), high dose§§						
Fluzone High-Dose	Sanofi Pasteur	0.5 mL prefilled syringe	No	≥65 yrs	IM†	No
Recombinant influenza vaccine, quadrivalent (RIV4)¶¶						
FluBlok Quadrivalent	Sanofi Pasteur	0.5 mL prefilled syringe	No	≥18 yrs	IM†	No
Live attenuated influenza vaccine, quadrivalent (LAIV4)						
FluMist Quadrivalent	AstraZeneca	0.2 mL single-dose prefilled intranasal sprayer	No	2–49 yrs	NAS	No

Abbreviations: ACIP = Advisory Committee on Immunization Practices; IM = intramuscular; NAS = intranasal
* Immunization providers should consult Food and Drug Administration–approved prescribing information for 2018–19 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/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm. Availability of specific products and presentations might change and differ from what is described in this table and in the text of this report.
† 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 is available in the ACIP General Best Practice Guidelines for Immunization, available at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html.

TABLE 2. Contraindications and precautions to the use of influenza vaccines—United States, 2018-2019 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 or 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 or severe 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 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 are immunocompromised due to any cause (including immunosuppression caused by medications or by HIV infection) 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 or 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 2018–19 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 https://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 age-appropriate influenza vaccine (IIV, RIV, or LAIV) may be administered to persons with egg allergy of any severity (see Persons with a History of Egg Allergy for further recommendations and information).

FIGURE 1. Influenza vaccine dosing algorithm for children aged 6 months through 8 years – Advisory Committee on Immunization Practices, United States, 2018-2019 influenza season