Date:    September 4, 2019

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

Ryan Westergaard, MD, PhD, MPH
State Epidemiologist for Communicable Diseases

Re:  The 2019-2020 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 2019-2020 ACIP recommendations for the prevention and control of seasonal influenza with vaccines are:

1. 2019-2020 U.S. trivalent influenza vaccines will contain an A/Brisbane/02/2018 (H1N1)pdm09-like virus, an A/Kansas/14/2017 (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 and (H3N2) virus components from the previous season.

2. Two recent regulatory actions are described:
   - In October 2018, FDA approved an expanded age indication for Afluria Quadrivalent (IIV4). Previously licensed for persons aged ≥5 years, Afluria Quadrivalent (IIV4) is now licensed for persons aged ≥6 months. The dose volume is 0.25 mL per dose (containing 7.5 µg of HA per vaccine virus) for children aged 6 through 35 months and 0.5 mL per dose (containing 15 µg of HA per vaccine virus) for all persons aged ≥36 months (≥3 years).
   - In January 2019, FDA approved a change in dose volume for Fluzone Quadrivalent (IIV4). Previously the dose volume for children aged 6 through 35 months was 0.25 mL (containing 7.5 µg of HA per vaccine virus). Children aged 6 through 35 months who receive Fluzone Quadrivalent may now receive either 0.25 mL (containing 7.5 µg of HA per vaccine virus) or 0.5 mL (containing 15 µg of HA per vaccine virus) per dose. Children aged ≥36 months (≥3 years) and adults should receive 0.5 mL per dose.
The full ACIP Recommendations

The 2019-2020 ACIP recommendations for the prevention and control of seasonal influenza with vaccines were formally issued on August 23, 2019. This document can be downloaded from the MMWR website at: https://www.cdc.gov/mmwr/volumes/68/rr/rr6803a1.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 2019-2020 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 2019-2020 season are (Table 1):

- Quadrivalent inactivated influenza vaccine (IIV4)
  - Sanofi Pasteur (Fluzone® Quadrivalent)
  - GlaxoSmithKline (Fluarix® Quadrivalent)
  - GlaxoSmithKline (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®)
- 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 2019-2020 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 2020, because influenza was detected among Wisconsin residents during 50 weeks of 2018 (the most current year for which we have complete data). Not all influenza vaccines are likely to be uniformly available in any given practice setting or geographic locality. Vaccination should not be delayed to obtain a specific product when an appropriate one is already available. To avoid missed opportunities for vaccination, providers should offer vaccination during routine health care visits and hospitalizations when vaccine is available. See Table 2 for a list of contraindications and precautions to receipt of influenza vaccine.

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 2019-2020 ACIP Recommendations include four principal updates: 

1. 2019-2020 U.S. trivalent influenza vaccines will contain an A/Brisbane/02/2018 (H1N1)pdm09-like virus, an A/Kansas/14/2017 (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.

3. Two recent regulatory actions are described:
   - In October 2018, FDA approved an expanded age indication for Afluria Quadrivalent (IIV4). Previously licensed for persons aged ≥5 years, Afluria Quadrivalent (IIV4) is now licensed for persons aged ≥6 months. The dose volume is 0.25 mL per dose (containing 7.5 µg of HA per vaccine virus) for children aged 6 through 35 months and 0.5 mL per dose (containing 15 µg of HA per vaccine virus) for all persons aged ≥36 months (≥3 years).
   - In January 2019, FDA approved a change in dose volume for Fluzone Quadrivalent (IIV4). Previously the dose volume for children aged 6 through 35 months was 0.25 mL (containing 7.5 µg of HA per vaccine virus). Children aged 6 through 35 months who receive Fluzone Quadrivalent may now receive either 0.25 mL (containing 7.5 µg of HA per vaccine virus) or 0.5 mL (containing 15 µg of HA per vaccine virus) per dose. Children aged ≥36 months (≥3 years) and adults should receive 0.5 mL per dose.

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 2019-2020 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.

References


<table>
<thead>
<tr>
<th>Trade name</th>
<th>Manufacturer</th>
<th>Presentation</th>
<th>Mercury (from thimerosal) (µg/0.5 mL)</th>
<th>Age indication</th>
<th>Route</th>
<th>HA (IIVs and RIV4) or virus count (LAIV4) for each vaccine virus (per dose)</th>
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</thead>
<tbody>
<tr>
<td><strong>Inactivated influenza vaccine, quadrivalent (IIV4), standard dose†</strong></td>
<td></td>
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<td>Afluria Quadrivalent</td>
<td>Seqirus</td>
<td>0.25 mL PFS</td>
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<td>6–35 mos</td>
<td>IM</td>
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<td>0.5 mL PFS</td>
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<td>≥3 yrs</td>
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<td>15 µg/0.5 mL</td>
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<td></td>
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<td>5.0 mL MDV</td>
<td>24.5</td>
<td>≥5 yrs (needle/syringe)</td>
<td>IM</td>
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<td>≥6 mos</td>
<td>IM</td>
<td>15 µg/0.5 mL</td>
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<td>FluLaval Quadrivalent</td>
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<td>--</td>
<td>≥6 mos</td>
<td>IM</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>5.0 mL MDV</td>
<td>&lt;25</td>
<td>≥6 mos</td>
<td>IM</td>
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<td>Fluzone Quadrivalent</td>
<td>Sanofi Pasteur</td>
<td>0.25 mL PFS**</td>
<td>--</td>
<td>6–35 mos</td>
<td>IM</td>
<td>7.5 µg/0.25 mL**</td>
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<td></td>
<td></td>
<td>0.5 mL PFS**</td>
<td>--</td>
<td>≥6 mos</td>
<td>IM</td>
<td>15 µg/0.5 mL**</td>
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<tr>
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<td></td>
<td>0.5 mL SDV**</td>
<td>--</td>
<td>≥6 mos</td>
<td>IM</td>
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<tr>
<td></td>
<td></td>
<td>5.0 mL MDV**</td>
<td>25</td>
<td>≥6 mos</td>
<td>IM</td>
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<td><strong>Inactivated influenza vaccine, cell culture-based (ccIIV4), standard dose†</strong></td>
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<td>Fluclavex Quadrivalent</td>
<td>Seqirus</td>
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<tr>
<td></td>
<td></td>
<td>5.0 mL MDV</td>
<td>25</td>
<td>≥4 yrs</td>
<td>IM</td>
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<td><strong>Adjuvanted inactivated influenza vaccine, trivalent (aIIV3), standard dose†</strong></td>
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<tr>
<td>Fluad</td>
<td>Seqirus</td>
<td>0.5 mL PFS</td>
<td>--</td>
<td>≥65 yrs</td>
<td>IM</td>
<td>15 µg/0.5 mL</td>
</tr>
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<td><strong>Inactivated influenza vaccine, trivalent (IIV3), high dose</strong></td>
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<td>Fluzone High-Dose</td>
<td>Sanofi Pasteur</td>
<td>0.5 mL PFS</td>
<td>--</td>
<td>≥65 yrs</td>
<td>IM</td>
<td>60 µg/0.5 mL</td>
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<td><strong>Recombinant influenza vaccine, quadrivalent (RIV4)¶¶</strong></td>
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<tr>
<td>FluBlok Quadrivalent</td>
<td>Sanofi Pasteur</td>
<td>0.5 mL PFS</td>
<td>--</td>
<td>≥18 yrs</td>
<td>IM</td>
<td>45 µg/0.5 mL</td>
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<tr>
<td><strong>Live attenuated influenza vaccine, quadrivalent† (LAIV4)</strong></td>
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<td>FluMist Quadrivalent</td>
<td>AstraZeneca</td>
<td>0.2 mL prefilled single-use intranasal sprayer</td>
<td>--</td>
<td>2–49 yrs</td>
<td>NAS</td>
<td>10^{6.5-7.5} fluorescent focus units/0.2 mL</td>
</tr>
</tbody>
</table>

**Abbreviations:** ACIP = Advisory Committee on Immunization Practices; FDA = Food and Drug Administration; HA = hemagglutinin; IIV3 = inactivated influenza vaccine, trivalent; IIV4 = inactivated influenza vaccine, quadrivalent; IM = intramuscular; LAIV4 = live attenuated influenza vaccine, quadrivalent; MDV = multidose vial; NAS = intranasal; PFS = prefilled syringe; RIV4 = recombinant influenza vaccine, quadrivalent; SDV = single-dose vial.

* Vaccination providers should consult FDA-approved prescribing information for 2019–20 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/vaccines-blood-biologics/approved-products/vaccines-licensed-use-united-statesexternal icon]. Availability of specific products and presentations might change and differ from what is described in this table and in the text of this report.

† Persons with a history of egg allergy may receive any licensed, recommended influenza vaccine that is otherwise appropriate for their age and health status. Those who report having had reactions to egg involving symptoms other than urticaria (e.g., angioedema or swelling, respiratory distress, lightheadedness, or recurrent emesis) or who...
required epinephrine or another emergency medical intervention should be vaccinated 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.

The dose volume for Afluria Quadrivalent is 0.25 mL for children aged 6 through 35 months and 0.5 mL for persons aged ≥3 years.

Intramuscularly-administered influenza vaccines should be given by needle and syringe only, with the exception of the MDV presentation of Afluria Quadrivalent, which may alternatively be given by the PharmaJet Stratis jet injector for persons aged 18 through 64 years only. For adults and older children, the recommended site for IM influenza vaccination is the deltoid muscle. The preferred site for infants and young children is the anterolateral aspect of the thigh. Additional guidance regarding site selection and needle length for intramuscular administration is available in the ACIP General Best Practice Guidelines for Immunization (https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf).

** Fluzone Quadrivalent may be given to children aged 6 through 35 months as either 0.25 mL per dose or 0.5 mL per dose. No preference is expressed for one or the other dose volume for this age group. Persons aged ≥3 years should receive the 0.5-mL dose volume.

### TABLE 2. Contraindications and precautions to the use of influenza vaccines—United States, 2019-2020 influenza season*

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Contraindications</th>
<th>Precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>IIV</td>
<td>History of severe allergic reaction to any component of the vaccine† or after previous dose of any influenza vaccine</td>
<td>Moderate or severe illness with or without fever History of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine</td>
</tr>
<tr>
<td>RIV4</td>
<td>History of severe allergic reaction to any component of the vaccine</td>
<td>Moderate or severe illness with or without fever History of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine</td>
</tr>
<tr>
<td>LAIV</td>
<td>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</td>
<td>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])</td>
</tr>
</tbody>
</table>

**Abbreviations:** ACIP = Advisory Committee on Immunization Practices; FDA = Food and Drug Administration; IIV = inactivated influenza vaccine; LAIV4 = live-attenuated influenza vaccine, quadrivalent; RIV4 = recombinant influenza vaccine, quadrivalent.

* Vaccination providers should check FDA-approved prescribing information for 2019–20 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/vaccines-blood-biologics/approved-products/vaccines-licensed-use-united-statesexternal icon.

† History of severe allergic reaction (e.g., anaphylaxis) to egg is a labeled contraindication to the use of most IIVs and LAIV4. However, ACIP recommends that persons with a history of egg allergy may receive any licensed, recommended influenza vaccine that is otherwise appropriate for their age and health status. Those who report having had reactions to egg involving symptoms other than urticaria (e.g., angioedema or swelling, respiratory distress, lightheadedness, or recurrent emesis) or who required epinephrine or another emergency medical intervention should be vaccinated 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.
FIGURE 1. Influenza vaccine dosing algorithm for children aged 6 months through 8 years – Advisory Committee on Immunization Practices, United States, 2019-2020 influenza season

Did the child receive ≥2 doses of trivalent or quadrivalent influenza vaccine before July 1, 2019? (Doses need not have been received during the same or consecutive seasons.)

Yes

1 dose of 2019–20 influenza vaccine

No or Don’t Know

2 doses of 2019–20 influenza vaccine (administered ≥4 weeks apart)

* For children aged 8 years who require 2 doses of vaccine, both doses should be administered even if the child turns age 9 years between receipt of dose 1 and dose 2.