

## 2021–22 ACIP Influenza Update

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## Preface

- Will focus on updates discussed at the June ACIP meeting.
- Draft language not considered recommendations until published in MMWR (anticipated in latter half of August).

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## 2021–22 Influenza Statement Updates Discussed June 2021

- Updates on the following topics:
  - Influenza vaccines expected to be available for the 2021-22 season
  - U.S. influenza vaccine viral composition for the 2021-22 season
  - Change in age indication for Flucelvax Quadrivalent from ≥4 years to ≥2 years
  - Timing of Vaccination language
  - Co-administration of influenza and COVID-19 vaccines
  - Contraindications and precautions concerning persons with previous severe allergic reaction to influenza vaccines

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### Influenza Vaccines Expected to be Available by Age Indication, United States, 2021–22 Influenza Season

Vaccine type		0 through 6 months	6 through 23 months	2 through 17 years	18 through 49 years	50 through 64 years	≥65 years	
IIV4s	Standard-dose, unadjuvanted inactivated (IIV4)		Afluria Quadrivalent Fluarix Quadrivalent FluLaval Quadrivalent Fluzone Quadrivalent					
	Cell culture-based inactivated (ccIIV4)				Flucelvax Quadrivalent			
	Adjuvanted inactivated (aIIV4)						Fluad Quadrivalent	
	High-dose inactivated (HD-IIV4)						Fluzone High-Dose Quadrivalent	
RIV4	Recombinant (RIV4)				Flublok Quadrivalent			
LAIV4	Live attenuated (LAIV4)			FluMist Quadrivalent				

IIV4=quadrivalent inactivated influenza vaccine RIV4=quadrivalent recombinant influenza vaccine LAIV4=quadrivalent live attenuated influenza vaccine

 Not approved for age group       Egg-based       Not egg-based

All vaccines expected for 2021-22 are quadrivalent (i.e., contain hemagglutinin derived from four viruses: one influenza A(H1N1), one influenza A(H3N2), one influenza B/Victoria and one influenza B/Yamagata.

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## 2021–22 Influenza Vaccine Composition

- **Egg-based IIV4s and LAIV4:**
  - An A/Victoria/2570/2019 (H1N1)pdm09-like virus; <sup>UPDATED</sup>
  - An A/Cambodia/e0826360/2020 (H3N2)-like virus; <sup>UPDATED</sup>
  - A B/Washington/02/2019 (Victoria lineage)-like virus; and
  - A B/Phuket/3073/2013 (Yamagata lineage)-like virus.
- **Cell-culture-based IIV4 and RIV4:**
  - An A/Wisconsin/588/2019 (H1N1)pdm09-like virus; <sup>UPDATED</sup>
  - An A/Cambodia/e0826360/2020 (H3N2)-like virus; <sup>UPDATED</sup>
  - A B/Washington/02/2019 (Victoria lineage)-like virus; and
  - A B/Phuket/3073/2013 (Yamagata lineage)-like virus.

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## Change in Age Indication for Flucelvax Quadrivalent

Cell culture-based inactivated influenza vaccine (ccIIV4).

- Previously licensed for ages  $\geq 4$  years; approved in March 2021 for ages  $\geq 2$  years.
- Change supported by randomized trial conducted among over 4,000 children aged  $\geq 2$  through  $< 18$  years over three influenza seasons: (Southern Hemisphere 2017 and Northern Hemisphere 2017-18 and 2018-19).
- Overall vaccine efficacy 54.6% (95%CI 45.7—62.1) against RT-PCR or culture-confirmed influenza-associated CDC-defined influenza-like illness.
- New age indication reflected in text and in Table 1 in draft Statement

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## Co-administration of Influenza Vaccines with COVID-19 Vaccines

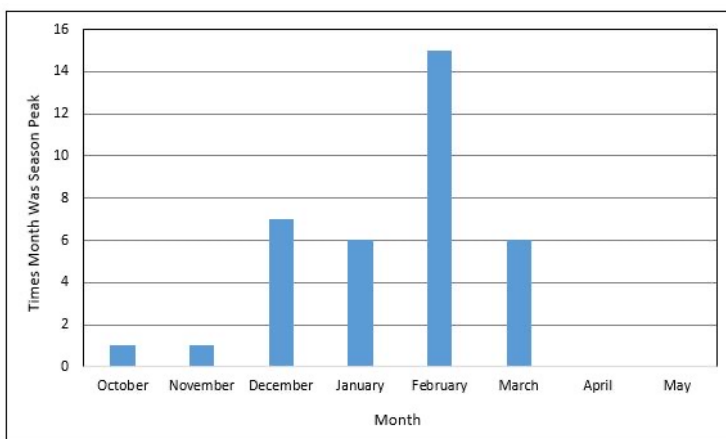
- Current CDC guidance indicates that COVID-19 vaccines and other vaccines may be administered without regard to timing.
- Draft statement reflects the CDC guidance.
- Notes that providers should check current CDC COVID-19 vaccination guidance for updated information concerning co-administration.

<https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

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## Timing of Influenza Seasons

- Timing of the onset and peak of influenza activity varies from season to season
- Timing of activity onset can also vary geographically
- In the United States, localized areas of increased activity occur as early as October
- Over the 36 seasons between 1982-83 and 2017-18, peak activity occurred in:<sup>1</sup>



- December 7 (19%) seasons
- January 6 (17%) seasons
- February 15 (42%) seasons
- March 6 (19%) seasons

<sup>1</sup>--<https://www.cdc.gov/flu/about/season/flu-season.htm>

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## Timing of Influenza Vaccination—Previous Language

- Vaccination has been recommended to be offered by the end of October, and to continue as long as influenza viruses are circulating locally
- Language has included recommendation that July and August are probably too early for vaccination in most influenza seasons, particularly for older adults.
  - Exception made for those children ages 6 months through 8 years who require two doses for the season, for whom receipt of the first dose is recommended as soon as possible after vaccine is available (since doses must be  $\geq 4$  weeks apart).

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## Factors Relevant for Timing of Vaccination

- Draft statement contains a discussion of evidence for waning protection following vaccination
  - Declines in influenza vaccine effectiveness over the course of the season have been observed in many observational studies.
  - Appears to be more pronounced among older adults
  - Less evidence for waning among children
- Also discusses other considerations related to timing
  - Unpredictability of timing of onset and peak of the influenza season
  - Avoiding missed opportunities to vaccinate
  - Programmatic constraints

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## Draft Timing Language and Early Vaccination (July/August)

- For all, vaccination should be offered ideally by the end of October.
- Children who need 2 doses (those aged 6 months through 8 years who have never been vaccinated or who have not received  $\geq 2$  total doses previously)—should receive first dose as soon as possible after vaccine is available.
- Children needing one dose can also be vaccinated as soon as vaccine is available
- Vaccination soon after vaccine becomes available can be considered for pregnant persons in third trimester
- For non-pregnant adults, July and August should be avoided unless there is concern that later vaccination might not be possible.
- Vaccination should continue throughout the season, as long as influenza viruses are circulating and unexpired vaccine is available.

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## Allergic Reactions to Influenza Vaccines--Background

- Vaccines (including influenza vaccines) include multiple components that can potentially trigger severe allergic reactions (e.g., anaphylaxis)
- Serious allergic reactions to influenza vaccine are rare
  - In one Vaccine Safety Datalink (VSD) study<sup>1</sup> the estimated rates of post-vaccination anaphylaxis among cases that involved administration of a single vaccine were:
    - 1.31 cases per million doses for all vaccines
    - 1.35 cases per million doses for IIV3

1--McNeil J Allerg Clin Immunol 2016;137:868-878

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## Influenza Vaccine Package Insert Language Concerning Previous Allergic Reactions to Influenza Vaccines

- Egg-based IIV4s and LAIV4: History of severe allergic reaction (e.g., anaphylaxis) **to any component of the vaccine** or to a previous dose of any influenza vaccine.
- cclIV4 and RIV4: History of severe allergic reaction (e.g., anaphylaxis) **to any component** of the vaccine

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## Contraindications and Precautions Related to Previous Severe Allergic Reaction to Influenza Vaccines

- For egg-based IIV4s and LAIV4: Severe allergic reaction to a previous dose of **any** influenza vaccine is a contraindication.
- For cclIV4: Severe allergic reaction to any cclIV is a contraindication; to any other influenza vaccine (any egg-based IIV, RIV, or LAIV) is a precaution.
- For RIV4: Severe allergic reaction to any RIV is a contraindication; to any other influenza vaccine (any egg-based IIV, cclIV, or LAIV) is a precaution.
- Where a precaution is present, if potential benefit of vaccination is thought to outweigh potential risk of a severe allergic reaction
  - Vaccination should occur in a medical setting supervised by a provider who can recognize and manage a severe allergic reaction.
  - Providers can also consider consulting an allergist to help identify the vaccine component responsible for the previous reaction

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## Contraindications and Precautions Related to Previous Severe Allergic Reaction to Influenza Vaccines

- Stated another way, in the following situations where a precaution exists, **and** if potential benefits of vaccination are believed to outweigh risks:
  - For those with previous severe allergic reaction to an egg-based IIV or LAIV, cclIV4 or RIV4 can be considered
  - For those with previous severe allergic reaction to a cclIV, RIV4 can be considered
  - For those with previous severe allergic reaction to an RIV, cclIV4 can be considered
- In each instance, when vaccinating in setting of a precaution:
  - Vaccination should occur in a medical setting supervised by a provider who can recognize and manage a severe allergic reaction
  - Allergist consultation can also be considered to help identify the component responsible for the previous reaction
- Importantly, each vaccine is contraindicated in the setting of previous severe allergic reaction to any component of that vaccine

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*Thank you!*

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