



Influenza Work Group:

Summary and Proposed Recommendations for the 2022-23 Influenza Season

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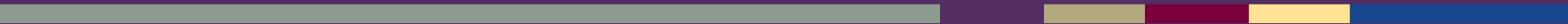
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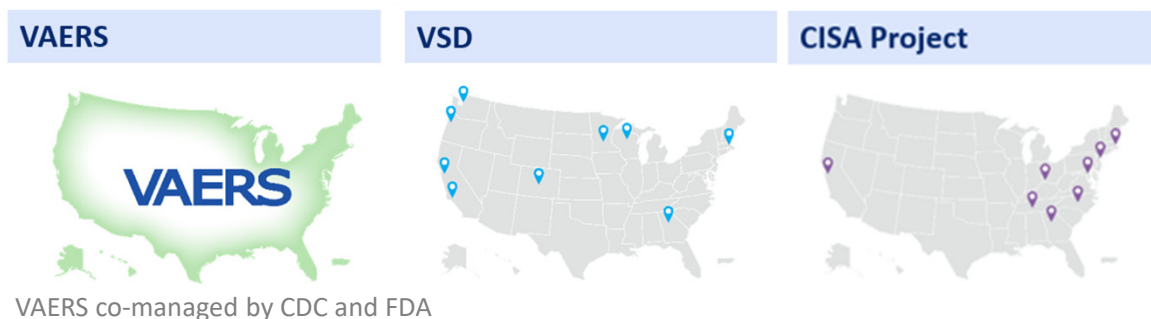


Influenza Vaccine Safety Update



Vaccine Safety Update: 2021-2022 Influenza Season

- ~175 million doses of influenza vaccine distributed in United States*
- Vaccine Adverse Event Reporting System (VAERS)
 - No new safety concerns identified
- Vaccine Safety Datalink (VSD)
 - ~5,550,000 doses of influenza vaccine administered in VSD
 - No new safety concerns identified**



* [Weekly Flu Vaccination Dashboard](#) | [FluVaxView](#) | [Seasonal Influenza \(Flu\)](#) | [CDC](#)

**Outcomes monitored in VSD: Acute disseminated encephalomyelitis, anaphylaxis, Bell's Palsy, encephalitis, Guillain-Barré syndrome, seizures, transverse myelitis

Vaccine Safety Update: 2021-2022 Influenza Season (continued)

- Clinical Immunization Safety Assessment (CISA) Project: studies enrolling in 2021-2022 influenza season
 - Safety of Simultaneous versus Sequential Administration of mRNA COVID-19 Vaccines and Quadrivalent Inactivated Influenza (IIV4) (Registered on ClinicalTrials.gov: [NCT05028361](https://clinicaltrials.gov/ct2/show/study/NCT05028361))*
 - Enrolled 73 participants aged ≥ 12 years during 2021-22 season; not currently enrolling
 - Safety panel assessment: no safety concerns
 - Study will resume enrollment during 2022-23 influenza season
 - Safety of Simultaneous Vaccination with Zoster Vaccine Recombinant (RZV) and Quadrivalent Adjuvanted Inactivated Influenza Vaccine (aIIV4) (Registered on ClinicalTrials.gov: [NCT05007041](https://clinicaltrials.gov/ct2/show/study/NCT05007041))**
 - Enrolled 102 participants aged ≥ 65 years during 2021-22 season; not currently enrolling
 - Safety panel assessment: no safety concerns
 - Study will resume enrollment during 2022-23 influenza season

*CISA study sites are Duke University, Cincinnati Children's Hospital Medical Center, John Hopkins University; safety panel included independent subject matters experts in vaccine safety, pediatric and adult infectious diseases and geriatric medicine; individual opinions provided

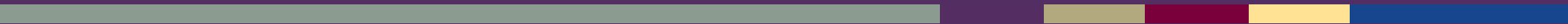
** CISA study sites are Duke University and John Hopkins University; safety panel included independent subject matters experts in vaccine safety and pediatric and adult infectious diseases; individual opinions provided

Acknowledgement

- VAERS Team
- Vaccine Safety Datalink (VSD) Team
- Clinical Immunization Safety Assessment (CISA) Project
- CDC Immunization Safety Office
- CDC Influenza Division
- FDA/Center for Biologics Evaluation and Research

We especially thank healthcare providers and health departments for reporting to VAERS and individuals for participating in clinical studies

Proposed Recommendations, 2022-23



Overview

- US influenza vaccine composition for 2022-23.
- Change in approved age indication for Flucelvax Quadrivalent (cclIV4).
- Recommendations for influenza vaccination of persons aged ≥ 65 years.



US Influenza Vaccine Composition for 2022-23

- All vaccines will be quadrivalent.
- Influenza A(H3N2) and influenza B/Victoria components updated.

2021-22	2022-23
<i>Egg-based IIV4s and LAIV4:</i>	<i>Egg-based IIV4s and LAIV4:</i>
A/Victoria/2570/2019 (H1N1)pdm09-like	A/Victoria/2570/2019 (H1N1)pdm09-like
A/Cambodia/e0826360/2020 (H3N2)-like	A/Darwin/9/2021 (H3N2)-like
B/Washington/02/2019 (Victoria lineage)-like	B/Austria/1359417/2021 (Victoria lineage)-like
B/Phuket/3073/2013 (Yamagata lineage)-like	B/Phuket/3073/2013 (Yamagata lineage)-like
<i>Cell-culture-based IIV4 and RIV4:</i>	<i>Cell-culture-based IIV4 and RIV4:</i>
A/Wisconsin/588/2019 (H1N1)pdm09-like	A/Wisconsin/588/2019 (H1N1)pdm09-like
A/Cambodia/e0826360/2020 (H3N2)-like	A/Darwin/6/2021 (H3N2)-like
B/Washington/02/2019 (Victoria lineage)-like	B/Austria/1359417/2021 (Victoria lineage)-like
B/Phuket/3073/2013 (Yamagata lineage)-like	B/Phuket/3073/2013 (Yamagata lineage)-like

Red type denotes change compared 2021-22.

<https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-march-3-2022-meeting-announcement#event-materials>


Change in Age Indication for Flucelvax Quadrivalent

- Cell-culture based quadrivalent inactivated influenza vaccine (ccIIV4).
 - Previously approved for ages ≥ 4 years; approved in March 2021 for ages ≥ 2 years.
 - Approved in October 2021 for ages ≥ 6 months.
- All standard-dose unadjuvanted IIV4s now approved for ages ≥ 6 months.

Influenza Vaccination for Persons Aged ≥ 65 Years

Proposed language:

ACIP recommends that adults aged ≥ 65 years should receive one of the following higher dose or adjuvanted influenza vaccines, if available: quadrivalent high-dose inactivated influenza vaccine (HD-IIV4), quadrivalent recombinant influenza vaccine (RIV4), or quadrivalent adjuvanted inactivated influenza vaccine (aIIV4). No preference is expressed for any one of these three vaccines over the other two. If none of these three vaccines is available at an opportunity for vaccine administration, then any other age-appropriate influenza vaccine should be used.



For more information, contact CDC
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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

