

Influenza Virus Vaccine Strain Selection 2023-2024 Northern Hemisphere

Vaccines and Related Biological Products Advisory Committee (3/7/2023)

> Jerry P Weir, PhD, Director Division of Viral Products/OVRR/CBER/FDA

Purpose of Today's VRBPAC Committee Discussion



- Review influenza surveillance and epidemiology data, genetic and antigenic characteristics of recent virus isolates, serological responses to current vaccines, and the availability of candidate vaccine strains and reagents
- Make recommendations for the strains of influenza A (H1N1 and H3N2) and B viruses to be included in 2023-2024 influenza vaccines licensed for use in the United States

Types of Analyses Used for Vaccine Strain Selection



- Epidemiology of circulating strains
 - Surveillance data from U.S. and around the world
- Antigenic relationships among contemporary viruses and candidate vaccine strains
 - Hemagglutination inhibition (HI) or Microneutralization (MN) tests using post-infection ferret sera
 - HI or MN tests using panels of sera from humans receiving recent influenza vaccines
 - Antigenic cartography
 - Phylogenetic analyses of HA and NA genes
 - Vaccine effectiveness

Previous Recommendations for Northern Hemisphere Influenza Vaccines – 2022-2023

- WHO recommendation February 25, 2022
- VRBPAC recommendation for the antigenic composition of the 2022-2023 influenza virus vaccines in the U.S. (March 3, 2022)
 - Influenza A (H1N1)
 - an A/Victoria/2570/2019 (H1N1)pdm09-like virus (Egg-based Vaccines)
 - an A/Wisconsin/588/2019 (H1N1)pdm09-like virus (Cell- or Recombinant-based Vaccines)
 - Influenza A (H3N2)
 - an A/Darwin/9/2021 (H3N2)-like virus (Egg-based Vaccines)
 - an A/Darwin/6/2021 (H3N2)-like virus (Cell- or Recombinant-based Vaccines)
 - Influenza B (for trivalent and quadrivalent vaccines)
 - a B/Austria/1359417/2021-like virus (B/Victoria lineage)
 - Influenza B (for quadrivalent vaccines containing the above 3 virus strains)
 - a B/Phuket/3073/2013-like virus (Yamagata lineage)



WHO Recommendations for 2023-2024 Northern Hemisphere Influenza Vaccine

- WHO recommendation February 24, 2023
- Recommended that vaccines for use in the 2023 2024 northern hemisphere influenza season contain the following:
 - Influenza A (H1N1)
 - an A/Victoria/4897/2022 (H1N1)pdm09-like virus (Egg-based Vaccines)
 - an A/Wisconsin/67/2022 (H1N1)pdm09-like virus (Cell- or Recombinant-based Vaccines)
 - Influenza A (H3N2)
 - an A/Darwin/9/2021 (H3N2)-like virus (Egg-based Vaccines)
 - an A/Darwin/6/2021 (H3N2)-like virus (Cell- or Recombinant-based Vaccines)
 - Influenza B (for trivalent and quadrivalent vaccines)
 - a B/Austria/1359417/2021-like virus (B/Victoria lineage)
 - Influenza B (for quadrivalent vaccines containing the above 3 virus strains)
 - a B/Phuket/3073/2013-like virus (Yamagata lineage)



Committee Discussion

• Which influenza strains should be recommended for the antigenic composition of the 2023-2024 influenza virus vaccine in the U.S.?

Options for Strain Composition for 2023-2024 Influenza Vaccines

- Influenza A (H1N1)
 - Recommend an A/Victoria/4897/2022 (H1N1)pdm09-like virus for egg-based vaccines
 - Recommend an A/Wisconsin/67/2019 (H1N1)pdm09-like virus for cell- or recombinant-based vaccines
 - Recommend alternative H1N1 candidate vaccine viruses
- Influenza A (H3N2)
 - Recommend an an A/Darwin/9/2021 (H3N2)-like virus for egg-based vaccines
 - Recommend an an A/Darwin/6/2021 (H3N2)-like virus for cell- or recombinant-based vaccines
 - Recommend alternative H3N2 candidate vaccine viruses
- Influenza B (for trivalent and quadrivalent vaccines)
 - Recommend a B/Austria/1359417/2021-like virus (B/Victoria lineage)
 - Recommend an alternative candidate vaccine virus from the B/Victoria lineage
 - Recommend a candidate vaccine virus from the B/Yamagata lineage
- Influenza B (2nd B strain for quadrivalent vaccines containing the above 3 viruses)
 - Recommend a B/Phuket/3073/2013-like virus (Yamagata lineage)
 - Recommend an alternative candidate vaccine virus from the B/Yamagata lineage
 - Recommend a candidate vaccine virus from the B/Victoria lineage

www.fda.gov



Voting Questions for the Committee

1) For the influenza A (H1N1) component of the 2023-2024 influenza virus vaccines in the U.S., does the committee recommend:

- an A/Victoria/4897/2022 (H1N1)pdm09-like virus (Egg-based Vaccines)
- an A/Wisconsin/67/2019 (H1N1)pdm09-like virus (Cell- or Recombinant-based Vaccines)

2) For the influenza A (H3N2) component of the 2023-2024 influenza virus vaccine in the U.S., does the committee recommend:

- an A/Darwin/9/2021 (H3N2)-like virus (Egg-based Vaccines)
- an A/Darwin/6/2021 (H3N2)-like virus (Cell- or Recombinant-based Vaccines)

3) For the influenza B component of the 2023-2024 trivalent and quadrivalent influenza virus vaccines in the U.S., does the committee recommend inclusion of a B/Austria/1359417/2021-like virus (B/Victoria lineage)

4) For quadrivalent 2023-2024 influenza vaccines in the U.S., does the committee recommend inclusion of a B/Phuket/3073/2013-like virus (B/Yamagata lineage) as the 2nd influenza B strain in the vaccine