Influenza Virus Vaccine
Strain Selection – 2024 Southern Hemisphere

Vaccines and Related Biological Products Advisory Committee (10/5/2023)

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

Agenda

- Introduction
- Global Influenza Virus Surveillance and Characterization
  - WHO Collaborating Center for Surveillance, Epidemiology and Control of Influenza
- Discussion topic - Challenges and Opportunities for Vaccine Strain Composition with the Reduced Public Health Threat from Influenza B/Yamagata Lineage Viruses
  - Comments from Manufacturers Representative
  - FDA Perspective
- Committee Discussion and Voting

Purpose of Today's VRBPAC Committee Discussion

- Make recommendations for the strains of influenza A (H1N1 and H3N2) and B viruses to be included in the 2024 Southern Hemisphere formulation of influenza vaccine licensed in the United States
  - Since 2016, two U.S. vaccine manufacturers have been approved to produce Southern Hemisphere formulations of their influenza vaccine (Sanofi Fluzone and Seqirus Afluria)
  - Both vaccines are quadrivalent and produced in eggs
  - Strain recommendation and supplement approval for SH formulations follow the Northern Hemisphere process using the most recent WHO recommendations as a guide
- Discuss the challenges and opportunities for vaccine strain composition with the reduced public health threat from influenza B/Yamagata lineage viruses
  - No B/Yamagata lineage viruses have been detected in >3 years
  - The VRBPAC, in previous meetings, and WHO experts at the most recent strain composition meeting, have advocated for vaccine composition changes that include removal of the B/Yamagata component, as well as consideration of other composition possibilities

Most Recent Recommendations for Northern Hemisphere Influenza Vaccines - 2023-2024

- WHO recommendation – February 24, 2023
- VRBPAC recommendation for the antigenic composition of the 2023-2024 influenza virus vaccines in the U.S. (March 7, 2023)
  - 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)

WHO Recommendations for Southern Hemisphere Influenza Vaccines - 2024

- WHO recommendation – 9/29/2023
- Recommended that trivalent egg-based vaccines for use in the southern hemisphere influenza season contain:
  - An A/Victoria/4897/2022 (H1N1)pdm09-like virus;
  - An A/Thailand/8/2022 (H3N2)-like virus; and
  - A B/Austria/1359417/2021 (B/Victoria lineage)-like virus
- "The recommendation for the B/Yamagata lineage component of quadrivalent influenza vaccines remains unchanged from previous recommendations:"
  - A B/Phuket/3073/2013 (B/Yamagata lineage)-like virus

- The WHO influenza vaccine composition advisory committee expressed the opinion that "inclusion of a B/Yamagata lineage antigen in quadrivalent influenza vaccines is no longer warranted, and that every effort should be made to exclude this component as soon as possible."

Discussion Topic for the Committee

- Please discuss possible changes to the antigen composition of future seasonal influenza vaccines:
  - The advantages versus the disadvantages of retaining the B/Yamagata lineage component in the quadrivalent influenza vaccine
  - The timing for possible removal of the B/Yamagata lineage component from the current quadrivalent formulation
  - The opportunities and challenges for alternative vaccine composition formulations and the data needed to support such changes

Voting Questions for the Committee

1. Does the committee recommend excluding the B/Yamagata lineage antigen component from quadrivalent influenza vaccines as soon as possible

2. For the composition of egg-based trivalent 2024 SH formulations of influenza vaccines, does the committee recommend:
   - Inclusion of an A/Victoria/4897/2022 (H1N1)pdm09-like virus;
   - Inclusion of an A/Thailand/8/2022 (H3N2)-like virus; and
   - Inclusion of a B/Austria/1359417/2021 (B/Victoria lineage)-like virus

3. For quadrivalent 2024 SH formulations of influenza vaccines, does the committee recommend:
   - Inclusion of a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus as the 2nd influenza B strain in the vaccine


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