

# Influenza Virus Vaccine 2010-2011 Strain Selection



**Vaccines and Related Biological Products Advisory  
Committee (2/22/2010)**

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# Purpose of Today's VRBPAC Committee Discussion

- Review influenza surveillance and epidemiology data, 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 2010-2011 influenza vaccines for use in the United States

# Review of the 2009-2010 Influenza Vaccine Strain Selection Process

- VRBPAC strain selection – 2/18/2009
  - Committee recommended the following strains for inclusion in U.S. 2009-2010 trivalent influenza vaccines
    - A/Brisbane/59/2007 (H1N1)-like virus
    - A/Brisbane/10/2007 (H3N2)-like virus
    - B/Brisbane/60/2008-like virus (B/Victoria lineage) – *change from 2008-2009 vaccine recommendation*
- Emergence of a novel H1N1 virus
  - Rapid spread from North America throughout world from April 2009
  - WHO strain recommendation for development of vaccines against the pandemic (H1N1) 2009 virus on May 26, 2009
  - WHO declaration of a pandemic on June 11, 2009
- VRBPAC – 7/23/2009
  - Committee convened to discuss pandemic H1N1 situation and planned clinical trials to support use of vaccines containing A/California/7/2009 (H1N1)v-like virus

# Review of the 2009-2010 Influenza Vaccine Strain Selection Process – Cont.

- Vaccine Approvals
  - July 2009 – Strain change supplements for trivalent formulations approved (all 6 U.S. manufacturers)
  - September 15, 2009 – Strain change supplements for pandemic monovalent formulation approved (4 U.S. manufacturers)
  - November 11, 2009 – Strain change supplement for pandemic monovalent formulation approved (5<sup>th</sup> U.S. manufacturer)
- WHO Recommendations for Southern Hemisphere 2010 – September 2009
  - A/California/7/2009 (H1N1)-like virus – *change from NH vaccine recommendation*
  - A/Perth/16/2009 (H3N2)-like virus – *change from NH vaccine recommendation*
  - B/Brisbane/60/2008-like virus

# 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) tests using post-infection ferret sera
  - Virus neutralization tests
  - HI tests using panels of sera from humans receiving TIV
  - Antigenic cartography
  - Phylogenetic analyses of HA and NA genes
- Availability and characteristics of egg-derived vaccine strains and high-growth reassortants
  - Availability of potency reagents for inactivated vaccines

# WHO Recommendations for Influenza Vaccine Composition Northern Hemisphere: 2010-2011

- “It is recommended that the following viruses be used for influenza vaccines in the 2010-2011 influenza season (northern hemisphere winter):
  - an A/California/7/2009 (H1N1)-like virus
  - an A/Perth/16/2009 (H3N2)-like virus
  - a B/Brisbane/60/2008-like virus”
- “As in previous years, national or regional control authorities approve the composition and formulation of vaccines used in each country”
  - VRBPAC and CBER for the U.S.

# Committee Discussion

- Which influenza strains should be recommended for the antigenic composition of the 2010-2011 influenza virus vaccine in the U.S.?
- Data to be considered includes:
  - the epidemiology of circulating influenza viruses
  - the antigenic characteristics of influenza virus strains currently circulating in human populations
  - the serologic responses to circulating influenza viruses of persons immunized with current influenza virus vaccines
  - the availability of suitable vaccine candidate strains

# Options for Strain Composition for 2010-2011 Influenza Vaccines

- Influenza A (H1N1)
  - Retain current vaccine strain A/Brisbane/59/2007 (H1N1)-like virus
    - e.g., A/Brisbane/59/2007; A/South Dakota/6/2007
  - Replace current vaccine strain with a pandemic A (H1N1) vaccine virus A/California/7/2009-like virus
    - Other candidates?
- Influenza A (H3N2)
  - Retain current strain A/Brisbane/10/2007 (H3N2)-like virus
    - e.g., A/Brisbane/10/2007; A/Uruguay/716/2007
  - Replace current vaccine strain with the Southern hemisphere vaccine virus A/Perth/16/2009 (H3N2)-like virus
    - e.g., A/Perth/16/2009; A/Wisconsin/15/2009
    - Other candidates?
- Influenza B
  - Retain current B/Brisbane/60/2008-like virus (B/Victoria lineage)
    - e.g., B/Brisbane/60/2008; B/Brisbane/33/2008
  - Replace current vaccine strain with alternative vaccine strain (B/Yamagata lineage)
    - Candidates?