FDA Panel: Same Flu Vaccine Strains Next Year

BY ELIZABETH MECHCATIE

FROM A MEETING OF THE FOOD AND DRUG ADMINISTRATION'S VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

BETHESDA, MD. – The influenza vaccine for the 2011-2012 influenza season in the United States should include the same three strains that are in the current vaccine, a Food and Drug Administration Advisory Panel recommended.

The panel voted to recommend that the strains in the Northern Hemisphere 2010-2011 seasonal influenza vaccine – an A/California/7/2009 (H1N1)–like virus, an A/Perth/16/2009 (H3N2)–like virus, and a B/Brisbane/60/2008–like virus – compose the upcoming vaccine.

This is a preliminary recommendation that will be approved by the FDA in time for vaccine manufacturers to be able to produce an adequate supply for next season. The vaccines panel meets at this time annually to make preliminary recommendations on the components of the trivalent vaccine for the forthcoming influenza season. It considers presentations on the latest influenza surveillance, and epidemiology data; antigenic characteristics of recent virus isolates; serologic responses to current vaccines; and availability of candidate vaccine strains and reagents.

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Influenza A(H3N2), A(H1N1), and B strains continue to circulate in the United States and globally, and recently characterized strains appear to be well matched to the components in the current seasonal vaccine, Dr. Lisa Grohskopf, a medical officer in the influenza division at the Centers for Disease Control and Prevention, Atlanta, said at the meeting. The H1N1 virus is a pandemic 2009 H1N1 virus and is the same vaccine virus as was used in the 2009 H1N1 monovalent vaccine.

Recently circulating viruses remain susceptible to neuraminidases, and in recent weeks, influenza activity has remained high, she said. An increase in the proportion of influenza A viruses identified as A(H1N1) have been identified since the beginning of the U.S. season. Of the viruses that have been tested at the CDC since Oct. 1, 2011, 13% have been influenza A(H1N1), 54% have been A(H3N2), and 33% have been influenza B.

The panel voted 15-0, with 1 abstention, in support of the H1N1 strain; the votes in favor of retaining the other two strains were unanimous. However, panelists expressed some concern about the B component, a B/Victoria lineage strain, because of the possibility that a B/Yamagata lineage strain could become an issue. As in past meetings, panelists observed that having a quadrivalent influenza vaccine, with both a B/Victoria and B/Yamagata component, would address these concerns. Although influenza vaccine manufacturers are conducting clinical studies of quadrivalent influenza vaccine, none would be ready for the next season, according to speakers at the meeting. One option discussed was to produce a monovalent vaccine to be used if needed to vaccinate susceptible groups, including children.

An industry representative who spoke at the meeting, Samson Lee, Ph.D., of Sanofi-Pasteur, said that there has been a significant increase in influenza immunization rates among different age groups during the current season, compared with last year: increases of about 18% in the pediatric population, 24% in adults, and 14% in the population aged 65 and older.

To date, 35 pediatric influenza-associated deaths have been reported in the United States this season, including 13 reportedly due to influenza B, 9 due to A(H3N2), and 7 due to A(H1N1). Subtyping was not performed for the remaining six cases, Dr. Grohskopf said.

Panel members reported having no relevant financial disclosures. ■