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WHAT'S NEW

Flu Vaccination for All Adults Endorsed for 2010-2011 Season

BY MIRIAM E. TUCKER

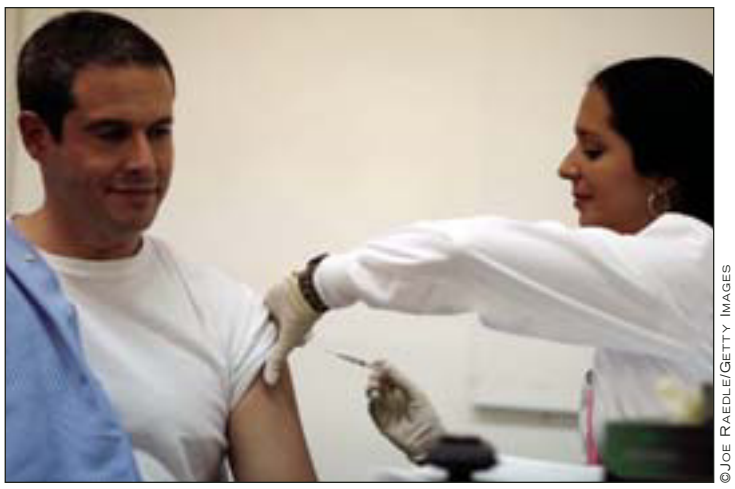
ATLANTA — The recommended target groups for annual influenza immunization have finally been broadened to include virtually the entire U.S. population.

Starting with the 2010-2011 season, universal immunization against influenza for everyone aged 6 months and older has the backing of the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention.

The committee voted unanimously (with one member abstaining) to recommend annual influenza immunization for people aged 19-49 years who had not already been targeted in previous recommendations. The new group comprises 15% of the U.S. population aged 6 months and older. About 50% of 19- to 49-year-olds already had indications for immunization, including individuals with chronic medical conditions, pregnant women, health care workers, and household contacts of high-risk individuals.

Despite previous recommendations aimed at expanded immunization of adults, "coverage among 19- to 49-year-olds has been low regardless of indication for vaccination," said Dr. Anthony Fiore of the CDC's National Center for Immunization and Respiratory Diseases.

Atlanta internist Sandra Fryhofer, American College of Physicians liasion to the ACIP, enthusiastically endorsed the move. "This is really exciting. It's about time, and it makes giving flu vaccines in the office much simpler. You won't have to wade through risk factors. The only decision will be whether you give a shot—the inactivated vaccine—or the live vaccine," she said in an interview.



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Healthy adults aged 19-49 years should receive the influenza vaccination annually, according to new recommendations.

Dr. Doug Campos-Outcalt, liaison to the ACIP from the American Academy of Family Physicians, expressed similar support. "We polled our members, and a very large majority is in favor of just a uniform [recommendation] because it will be so much easier to remember. The implementation with that 15% is not going to be a huge challenge," particularly with vaccination available at

See **Flu Vaccination** *page 4*

FDA Demands Tougher Labeling For Long-Acting Beta-Agonists

LABAs should be used only with an asthma-controller medication, such as an inhaled corticosteroid.

BY ELIZABETH MECHCATIE

The Food and Drug Administration is requiring major changes to the prescribing information for inhaled long-acting beta agonists as part of a risk management plan to address the ongoing safety issues associated with the products' use in children and adults with asthma, the agency said at a press briefing.

Safety concerns regarding long-acting beta agonist (LABA) therapy date back to a major study reported more than 7 years ago, and a 2008 FDA meta-analysis indicated that treatment with LABAs—either alone or combined with an inhaled corticosteroid (ICS)—is associated with an increased risk of severe asthma symptoms and hospitalizations as well as deaths in adults and children with asthma, compared with people not on a LABA.

The LABA products approved in the United States are Serevent (salmeterol) and Foradil (formoterol), which contain the LABA alone, and Advair (salmeterol plus fluticasone) and Symbicort (formoterol plus budesonide), which contain the LABA and an ICS.

Previous efforts to address these risks, including a boxed warning added in 2003, have not adequately addressed the safety issue, so the FDA is requiring label changes as part of a risk evaluation and mitigation strategy (REMS) for these products. The changes are "intended to better inform health care providers and patients with asthma about the risks of LABAs and the way they can decrease these risks while maintaining the benefits" of these drugs, Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research (CDER), said at the briefing.

See **Labeling** *page 7*

Target Population Simplified

Flu Vaccination *from page 1*

pharmacies and other alternative sites.

He added that the move should not overshadow the need to target health care workers specifically for influenza immunization. "All professional organizations need to work on that," said Dr. Campos-Outcalt, of the department of family and community medicine at the University of Arizona, Phoenix.

The ACIP vote was made amidst a confluence of factors, most notably the 2009 influenza A(H1N1) pandemic. About 90% of hospitalizations and deaths caused by the pandemic strain occurred among individuals younger than 65 years, many of them adults aged 19-49 years. It's likely that 2009 H1N1–like viruses will continue circulating in 2010-2011, and it's unknown what proportion of healthy adults now have immunity, Dr. Fiore said.

Adults aged 19-24 years had been among the targeted priority groups for the 2009 H1N1 monovalent vaccine. Obesity, which affects 28% of U.S. adults, was identified as a new independent risk factor for severe illness with the 2009 H1N1 strain, he noted.

The composition of the northern hemisphere's 2010-2011 seasonal influenza vaccine, which was announced at a recent Food and Drug Administration's Vaccines and Related Biological Products Advisory Committee meeting, will contain the same H1N1 virus used in the 2009 H1N1 monovalent vaccine.

Two newly licensed influenza vaccines and expanded age indications for two others should help ensure an adequate supply. These include Agriflu (Novartis) for adults 18 years and older and Fluzone High-Dose (Sanofi-Pasteur) for those aged 65 years and older. (See related story at right.) CSL's Afluria indication has been expanded to include people aged 6 months and older, and GlaxoSmithKline's Fluarix is now licensed for those aged 36 months and older, Dr. Fiore said.

"It's just exciting to have new things happening in flu," Dr. Fryhofer said. "This is a deadly disease that kills 36,000 people a year. It's great that now we have a uniform indication to get people protected, and that we have more things to protect them with and more companies making them, so hopefully we won't have more shortages and delays like we've had in the past." ■

Disclosures: *Dr. Fiore and Dr. Fryhofer had no financial disclosures. Dr. Campos-Outcalt has given vaccine talks for the France Foundation, an independent medical education company that receives grants from various sources.*

TALK BACK

How will your practice respond to the endorsement of universal influenza immunization?

Share your thoughts!
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High-Dose Flu Vaccine May Be Better for Older Adults

BY MIRIAM E. TUCKER

ATLANTA — Fluzone High-Dose vaccine was significantly more immunogenic than standard-dose influenza vaccine in a study of 3,876 individuals aged 65 years or older.

Sanofi-Pasteur's Fluzone High-Dose was licensed last December for use in that age group. In the phase III, multicenter, double-blind study, the participants were randomized in a 2:1 ratio to receive either high-dose (HD) vaccine containing 60 mcg hemagglutinin per strain or standard dose (SD) with 15 mcg hemagglutinin per strain. Blood specimens were obtained before vaccination and on day 28 for evaluation of influenza antibodies. Safety data were collected by diary card at 1-week and 4-week visits, and by telephone for up to 6 months after vaccination, Dr. David Greenberg said at a meeting of the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

VITALS

Major Finding: Fluzone High-Dose influenza vaccine was more immunogenic and reactogenic than the standard dose in adults aged 65 years and older.

Data Source: Phase III, multicenter, randomized, double-blind study of 3,876 participants.

Disclosures: The study was funded by Sanofi-Pasteur.

Reported injection site reactions within 7 days of vaccination were more common with HD. Pain was reported by 36% of the 2,573 participants who were assessed after receiving the HD vaccine and in 24% of the 1,260 in the SD group. Grade III pain was uncommon in both groups (0.3% with HD and 0.2% with SD). Erythema occurred in 15% with HD and 11% with SD, and swelling in 9% and 6%, respectively. Grade III erythema and swelling occurred in less than 2% of both groups. Most injection site reactions were mild to moderate and resolved within 3 days, said Dr. Greenberg, Sanofi-Pasteur's senior director of scientific and medical affairs.

Rates of systemic reactions were similar between the HD and SD groups, including myalgia (21% HD, 18% SD), malaise (18%, 14%), headache (17%, 14%), and fever (0%, 0.1%). Adverse events in the 30 minutes following vaccination were comparable (about 0.3% in both groups), as were rates of unsolicited adverse events within 28 days post vaccination (22% of both groups) (J. Infect. Dis. 2009;200:172-80).

Only two serious adverse events were reported by investigators as being vaccine-related: an exacerbation of Crohn's disease 2 days after receipt of HD vaccine, and a new diagnosis of myasthenia gravis 1 month after SD vaccination.

To satisfy requirements of the Food and Drug Administration, Fluzone was required to demonstrate superiority to SD vaccine for at least two of the three vaccine influenza strains, without inferiority for any strain. Fluzone achieved superiority—as determined by significantly greater geometric mean antibody titers—for the H1N1 and H3N2 strains and noninferiority for the B strain. The HD/SD geometric mean antibody titer ratios were 1.7 for H1N1, 1.8 for H3N2, and 1.3 for B, Dr. Greenberg reported.

The differences in immunogenicity were maintained for persons younger than 75 years vs. those 75 and older, for those with or without a history of cardiovascular or respiratory disease, and for both males and females, he added.

Sanofi-Pasteur began a 3-year randomized, blinded postlicensure efficacy trial of Fluzone High-Dose in September 2009. The vaccine will be available for the 2010-2011 flu immunization season.

Pandemic H1N1 Strain Gets Nod for 2010-2011 Flu Vaccine

BY ELIZABETH MECHCATIE

BETHESDA, MD. — The influenza vaccine for the 2010-2011 influenza season in the United States should include a pandemic influenza A(H1N1) strain, instead of one of the two seasonal influenza A strains in the current vaccine, a Food and Drug Administration advisory panel has recommended.

At a meeting of the FDA's Vaccines and Related Biological Products Advisory Committee, the panel unanimously voted 12-0 that the current influenza A(H1N1) strain included in the 2009-2010 seasonal flu vaccine, an A/Brisbane/59/2007 (H1N1)–like virus, should be replaced with a pandemic A(H1N1) vaccine virus, an A/California/7/2009–like virus, the component of the monovalent pandemic vaccine used this past season. Also included in the vaccine should be an A/Perth/16/2009 (H3N2)–like virus and a B/Brisbane/60/2008–like virus (B/Victoria lineage), the panel said.

The panel's recommendation is based on the finding that the vast majority of influenza A(H1N1) viruses circulating worldwide have been the pandemic strain. At the meeting, Nancy Cox, Ph.D., director of the influenza division at the Centers for Disease Control and Prevention, told the panel that there has been very little evidence of circulating seasonal A(H1N1) influenza viruses, which "most likely pose a low risk" in the forthcoming season in the northern hemisphere.

Seasonal A(H1N1) influenza viruses 'most likely pose a low risk' in the forthcoming season.

DR. COX

The panel meets every year at this time to make preliminary recommendations on the components of the trivalent vaccine for the forthcoming influenza season in the northern hemisphere. It considered information on the strains circulating worldwide as well as recommendations announced by the World Health Organization for the 2010-2011 influenza vaccine to be used in the northern hemisphere.

The panel voted to replace the influenza A(H3N2) strain included in the current vaccine with a southern hemisphere vaccine virus A/Perth/16/2009 (H3N2)–like virus. Dr. Cox said that activity of seasonal A(H3N2) viruses has been "relatively low" worldwide, compared with previous years, and what has been circulating antigenically is closely related to the A/Perth/16/2009 virus.

The panel voted to retain the influenza B component that is used in the current vaccine, a B/Brisbane/60/2008–like virus (B/Victoria lineage). Influenza B viruses have been circulating at low levels in many countries, but Victoria lineage viruses continue to predominate, Dr. Cox said. She pointed out, however, that it is always difficult to predict which lineage of influenza B viruses will predominate.

The panel's recommendations were the same as the WHO recommendations for the three components of the influenza vaccine for the forthcoming season in the northern hemisphere. ■

Pages 4a—4b