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WHAT'S NEW

Flu Vaccination for All Adults Endorsed for 2010-2011 Season

BY MIRIAM E. TUCKER

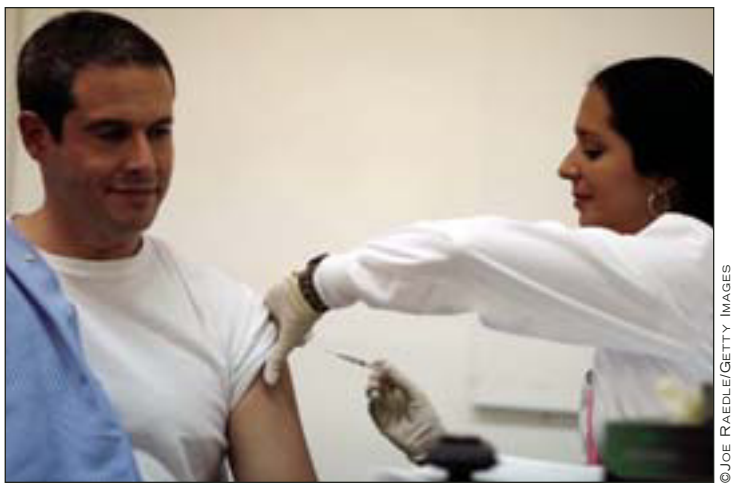
ATLANTA — The recommended target groups for annual influenza immunization have finally been broadened to include virtually the entire U.S. population.

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

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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.

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Promoting Safer Use of LABAs

Labeling *from page 1*

The new labeling states that:

► LABAs are not asthma-controller medications and are contraindicated without the use of an asthma-controller medication, such as an ICS. Single-agent LABAs should be used only with a controller medication, never alone.

► A LABA should be used only as long-term treatment in patients whose asthma cannot be adequately controlled on asthma-controller medications.

► Children and adolescents who need a LABA with an ICS should be prescribed one of the combination products, to ensure that a LABA is not used alone.

► LABAs should be used for the shortest period of time possible to achieve symptom control. As soon as a patient's asthma is under control, the LABA should be discontinued "if possible," and the patient should be maintained on an asthma-controller medication, such as an ICS. This is a change from current asthma treatment guidelines.

The REMS for these products includes a revised medication guide for patients that explains the product risks with each filled prescription, a plan to educate health care providers about the appropriate use of LABAs, and a requirement that the manufacturers conduct more studies of the safety of the LABA-ICS combination products.

Currently there are insufficient data to conclude whether LABAs combined with an ICS "reduces or eliminates the risk of asthma-related death and hospitalizations," the FDA statement said.

Under a recently launched drug safety initiative, the FDA will monitor the use of LABAs to determine whether they are still being used without a controller drug.

The new requirements do not apply to the use of LABAs for chronic obstructive pulmonary disease or intermittent exercise-induced broncospasm. ■

The full statement is available at www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm200776.htm.