

POLICY & PRACTICE

Groups Urge Child Focus in Election

Thirty of the nation's child-related organizations—including the American Academy of Pediatrics, Prevent Child Abuse America, Every Child Matters, and the National Association of Social Workers—pleaded for an election-year focus by candidates and the news media on the plight of millions of at-risk children and youths. Representatives of the groups pointed out at a press briefing that since the start of the wars in Afghanistan and Iraq, 28,000 U.S. children have died because of abuse, homicide, or suicide; 1.1 million more children

are living in poverty; and an additional 4.4 million families lack health insurance. "It's time for us to step up for kids," Dr. Renee Jenkins, AAP president, said at the briefing. "We do it in our everyday lives, but we need to do it in the political arena as well. As a nation, we're sorely lacking in our commitment to children."

Healthier Drinks Seen in Schools

The beverage industry has significantly reduced the number of high-calorie beverages available in schools, 2 years into the 3-year implementation of the national

School Beverage Guidelines, according to an independent evaluation. The Alliance for a Healthier Generation, a joint initiative of the William J. Clinton Foundation and the American Heart Association, worked with major beverage manufacturers to establish guidelines that limit portion sizes and reduce the number of calories from beverages available to children during the school day. The 2007-2008 progress report showed that the total number of calories in the beverages shipped to schools decreased by 58% since 2004, and that 79% of schools in contracts with bottlers already are in compliance with the guidelines. Under the guidelines, approved beverage options include 100% juice, low-fat milk, and bottled water in elementary and middle schools. High schools can add diet sodas, calorie-capped sports drinks and enhanced waters, and low-calorie teas.

Rx Monitoring Finds Problems

One-third of drugs studied as part of a Food and Drug Administration initiative designed to spur more testing in children required labeling changes or other actions to warn of side effects or other reactions in the pediatric population, a study found. The FDA initiative, approved as part of FDA legislation in 1997, grants an additional 6 months of marketing exclusivity to drug companies that agree to conduct studies of their drugs in the pediatric population. Researchers reporting in Pediatrics found that of 67 drugs granted exclusivity under that program, the FDA's Pediatric Advisory Committee recommended labeling changes for 12 drugs, continued monitoring for 10 drugs, and production of medication guides for 9 drugs. One drug also had an update to its label changes. Several of the adverse events revealed during the study process were rare and life threatening, the researchers said.

Special Needs Dental Center Opens

In an effort to provide better access to oral health care for patients with disabilities and to train the next generation of dental practitioners to care for them, the University of Pittsburgh School of Dental

Medicine has opened the Center for Patients With Special Needs. The center, which will offer services for those who are physically limited by birth defects, injury, or disease, as well as patients with intellectual and developmental disabilities, will be staffed by specialists from the departments of pediatric dentistry and anesthesiology. Specialty residents, predoctoral students, and dental-hygiene students will rotate through the center to expand the pool of future dental practitioners with skills to care for patients with special needs, according to the school.

SAMHSA Opens 5-Year Grant Program

The Substance Abuse and Mental Health Services Administration has opened Project LAUNCH (Linking Actions for Unmet Needs in Children's Health), a new grant program designed to promote the well-being of children from birth to age 8 by addressing the physical, emotional, social, and behavioral aspects of their development. More than \$27 million in grant funds will be awarded to state and tribal programs over the next 5 years, according to SAMHSA, with grantees each receiving approximately \$900,000 annually.

Foundation Launches Recess Project

The Robert Wood Johnson Foundation has announced an \$18 million investment in recess activities to improve children's health at 650 low-income schools. The foundation will team with Sports4Kids, a national nonprofit organization that pioneered an effective model for using play and classic games—such as kickball, four square, and tag—to transform the learning environment at elementary schools serving minority and low-income children. Sports4Kids puts trained adults on the playground to introduce the games, as well as to give kids simple tools, such as rock-paper-scissors, to avoid fights and keep the games going "An investment in bringing safe and healthy play back to school playgrounds ... reaps dividends for the entire community," said Dr. Risa Lavizzo-Mourey, president of the foundation.

—Jane Anderson

Nervous system disorders: Guillain-Barré syndrome, Bell's Palsy
Respiratory, thoracic and mediastinal disorders: Epistaxis
Skin and subcutaneous tissue disorders: Rash

DRUG INTERACTIONS

Aspirin Therapy

Do not administer FluMist to children or adolescents who are receiving aspirin therapy or aspirin-containing therapy.

Antiviral Agents Against Influenza A and/or B

The concurrent use of FluMist with antiviral agents that are active against influenza A and/or B viruses has not been evaluated. However, based upon the potential for antiviral agents to reduce the effectiveness of FluMist, do not administer FluMist until 48 hours after the cessation of antiviral therapy and antiviral agents should not be administered until two weeks after administration of FluMist unless medically indicated. If antiviral agents and FluMist are administered concomitantly, revaccination should be considered when appropriate.

Concomitant Inactivated Vaccines

The safety and immunogenicity of FluMist when administered concurrently with inactivated vaccines have not been determined. Studies of FluMist excluded subjects who received any inactivated or subunit vaccine within two weeks of enrollment. Therefore, healthcare providers should consider the risks and benefits of concurrent administration of FluMist with inactivated vaccines.

Concomitant Live Vaccines

Concurrent administration of FluMist with the measles, mumps and rubella vaccine and the varicella vaccine was studied in 1245 children 12-15 months of age. Adverse events were similar to those seen in other clinical trials with FluMist. No evidence of interference with immune responses to measles, mumps, rubella, varicella and FluMist vaccines was observed. The safety and immunogenicity in children >15 months of age have not been studied.

Intranasal Products

There are no data regarding co-administration of FluMist with other intranasal preparations.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C

Animal reproduction studies have not been conducted with FluMist. It is not known whether FluMist can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. FluMist should be given to a pregnant woman only if clearly needed.

The effect of the vaccine on embryo-fetal and pre-weaning development was evaluated in a developmental toxicity study using pregnant rats receiving the frozen formulation. Groups of animals were administered the vaccine either once (during the period of organogenesis on gestation day 6) or twice (prior to gestation and during the period of organogenesis on gestation day 6), 250 microliter/rat/occasion (approximately 110-140 human dose equivalents), by intranasal instillation. No adverse effects on pregnancy, parturition, lactation, embryo-fetal or pre-weaning development were observed. There were no vaccine related fetal malformations or other evidence of teratogenesis noted in this study.

Nursing Mothers

It is not known whether FluMist is excreted in human milk. Therefore, as some viruses are excreted in human milk and additionally, because of the possibility of shedding of vaccine virus and the close proximity of a nursing infant and mother, caution should be exercised if FluMist is administered to nursing mothers.

Pediatric Use

Safety and effectiveness of the vaccine has been demonstrated for children 2 years of age and older with reduction in culture-confirmed influenza rates compared to active control (injectable influenza vaccine made by Sanofi Pasteur Inc.) and placebo. FluMist is not indicated for use in children <24 months of age. FluMist use in children <24 months has been associated with increased risk of hospitalization and wheezing in clinical trials.

Geriatric Use

FluMist is not indicated for use in individuals ≥65 years of age. Subjects with underlying high-risk medical conditions (n=200) were studied for safety. Compared to controls, FluMist recipients had a higher rate of sore throat.

Use in Individuals 50-64 Years of Age

FluMist is not indicated for use in individuals 50-64 years of age. In Study AV009, effectiveness was not demonstrated in individuals 50-64 years of age (n=641). Solicited adverse events were similar in type and frequency to those reported in younger adults.

PATIENT COUNSELING INFORMATION

Vaccine recipients or their parents/guardians should be informed by the health care provider of the potential benefits and risks of FluMist, and the need for two doses at least 1 month apart in children 2-8 years old who have not previously received influenza vaccine.

Asthma and Recurrent Wheezing

Ask the vaccinee or their parent/guardian if the vaccinee has asthma. For children <5 years of age, also ask if the vaccinee has recurrent wheezing since this may be an asthma equivalent in this age group.

Vaccination with a Live Virus Vaccine

Vaccine recipients or their parents/guardians should be informed by the health care provider that FluMist is an attenuated live virus vaccine and has the potential for transmission to immunocompromised household contacts.

Adverse Event Reporting

The vaccine recipient or the parent/guardian accompanying the vaccine recipient should be told to report any suspected adverse events to the physician or clinic where the vaccine was administered.

FluMist® is a registered trademark of MedImmune, LLC.



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