Notice to Readers: Expansion of Use of Live Attenuated Influenza Vaccine (FluMist®) to Children Aged 2--4 Years and Other FluMist Changes for the 2007--08 Influenza Season

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On September 19, 2007, MedImmune Vaccines (Gaithersburg, Maryland) received approval from the Food and Drug Administration (FDA) to expand the use of FluMist®, a live, attenuated influenza vaccine (LAIV), to children aged 2--4 years (i.e., 24--49 months). FluMist is an intranasally administered influenza vaccine that was first licensed by the FDA in 2003 for healthy, nonpregnant persons aged 5--49 years (*1*). Expanding the age indications to include healthy children aged 2--4 years provides another influenza vaccination option for young children. In granting the new approval, FDA emphasized that FluMist is not approved for vaccination of children aged <2 years or adults aged >49 years, and that FluMist safety has not been established in persons with underlying medical conditions predisposing them to influenza-related complications (*2*). In addition, FluMist should not be administered to persons with asthma or children aged <5 years with recurrent wheezing (*1,2*).

New Recommendation for FluMist

In a randomized trial published in 2007, FluMist and trivalent inactivated vaccine (TIV) were compared among children aged 6--59 months (*3*). Children with medically diagnosed or treated wheezing within 42 days before enrollment, or a history of severe asthma, were excluded from this study. FluMist had a 55% (95% confidence interval [CI] = 45%--63%) greater efficacy compared with TIV in preventing culture-confirmed influenza illness.

In the trial, among children aged 6--23 months, wheezing that required bronchodilator therapy or that was associated with significant respiratory symptoms occurred in 5.9% of FluMist recipients, compared with 3.8% of those who received TIV (risk ratio [RR] = 1.5, CI = 1.2--2.1). Wheezing was not greater among children aged 24--59 months who received FluMist (*3*). In a previous randomized placebo-controlled safety trial among children aged 12 months--17 years, an elevated risk for asthma events (RR = 4.06, CI = 1.29--17.86) was noted among 728 children aged 18--35 months who received FluMist; of the 16 children with asthma-related events, none required hospitalization, and elevated risks for asthma were not observed in other age groups (*4*).

During 2006--2007, the Advisory Committee on Immunization Practices (ACIP) influenza vaccine workgroup reviewed data on the use of FluMist among children aged 2--4 years. On the basis of these data, expert opinion of the workgroup members, and consultation with representatives from the American Academy of Pediatrics and immunization safety experts, the workgroup revised recommendations for use of LAIV to include children aged 2--4 years, and presented its recommendations to ACIP. On October 24, 2007, ACIP recommended that

either LAIV or TIV can be used to vaccinate healthy non-pregnant persons aged 2--49 years. For the purposes of this recommendation, healthy persons were defined as persons who do not have an underlying medical condition that predisposes them to influenza complications (*5*). ACIP also approved use of FluMist for healthy persons aged 2--18 years under the federal Vaccines for Children (VFC) program.

Although FDA licensure of FluMist excluded children aged 2--4 years with a history of asthma or recurrent wheezing, the precise risk, if any, of wheezing caused by FluMist among these children is unknown because experience with FluMist among these young children is limited. Young children might not have a history of recurrent wheezing if their exposure to respiratory viruses has been limited because of their age. Certain children might have a history of wheezing with respiratory illnesses but have not had asthma diagnosed. The ACIP influenza vaccine workgroup, with advice from consultants, developed the following screening recommendations to assist persons who administer influenza vaccines in providing the appropriate vaccine for children aged 2--4 years.

Clinicians and immunization programs should screen for possible reactive airways diseases when considering use of FluMist for children aged 2--4 years, and should avoid use of this vaccine in children with asthma or a recent wheezing episode. Health-care providers should consult the medical record, when available, to identify children aged 2--4 years with asthma or recurrent wheezing that might indicate asthma. In addition, to identify children who might be at greater risk for asthma and possibly at increased risk for wheezing after receiving LAIV, parents or caregivers of children aged 2--4 years should be asked: "In the past 12 months, has a health-care provider ever told you that your child had wheezing or asthma?" Children whose parents or caregivers answer "yes" to this question and children who have asthma or who had a wheezing episode noted in the medical record within the past 12 months, should not receive FluMist. TIV is available for use in children with asthma or possible reactive airways diseases.

Other Changes in FluMist Use for 2007--08

Three other changes in the use of FluMist and its 2007--08 formulation should be noted; the amount of vaccine administered, the temperature at which FluMist is shipped and stored after delivery to the end-user, and the minimum interval between doses have changed compared with the 2006--07 influenza season formulation. First, FluMist is now supplied in a prefilled, single-use sprayer containing 0.2 mL of vaccine instead of the previous 0.5 mL dose. Persons administering FluMist should spray 0.1 mL (i.e., half of the total sprayer contents) into the first nostril while the recipient is in an upright position. An attached dose-divider clip should then be removed from the sprayer and the second half of the dose administered into the other nostril. Second, FluMist is now approved to be shipped to end users at 35°F--46°F (2°C--8°C) instead of being shipped and stored frozen. FluMist should be stored at 35°F--46°F (2°C--8°C) upon receipt, and can remain at that temperature until the expiration date is reached. (*2*) Third, the recommended interval from the first to the second dose in children requiring 2 doses has changed from a minimum of 6 weeks to a minimum of 4 weeks, the same interval recommended between doses for TIV (*2*).

Regardless of the vaccine used, ACIP, the American Academy of Pediatrics, and the American Academy of Family Physicians recommend that children aged <9 years who have not previously been administered an influenza vaccine should receive 2 doses separated by 4 or more weeks in the initial year (*6*). Children aged <9 years who did not receive the recommended second dose of influenza vaccine in the initial year that they received influenza vaccine should receive 2 doses separated by 4 or more weeks before or during the next influenza season. This recommendation applies only to the influenza season that follows the first season that a child aged <9 years receives influenza vaccine (*5,7*). Children aged <9 years who are being vaccinated two or more seasons after receiving an influenza vaccine for the first time should receive a single annual dose, regardless of the number of doses administered previously (*5,7*). Additional information is available from the manufacturer's package insert (*2*) and MedImmune Vaccines, telephone 877-358-6478.

References

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