

# Influenza vaccine: New recommendations for infants and children aged 6 to 23 months

**Doug Campos-Outcalt, MD, MPA**

University of Arizona Department of Family and Community Medicine, Phoenix

For the 2004–2005 influenza season, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) recommends that influenza vaccine be given to all infants and children aged 6 to 23 months.<sup>1</sup> It further recommends vaccination for members of households that have children aged <2 years and for out-of-home caregivers for these children.

These changes will make universal coverage more difficult to achieve. Family physicians will need to educate themselves, office staff, and parents and guardians about these recommendations. Be prepared to implement office protocols that identify and notify those who require vaccination, and address the concerns of parents and guardians regarding thimerosal and the addition of yet another vaccine to the child vaccine schedule.

## ■ RATIONALE FOR CHANGE

In 2002, ACIP began to encourage use of influenza vaccine for all children 6 to 23 month old. Before then, it had been recommended only for those in that age group with certain chronic medical conditions.

Still, the coverage level achieved in the 2002 to 2003 flu season for this age group was low—

only 4.4 % were fully immunized with 2 doses.<sup>2</sup> To increase coverage, the influenza vaccine was included in vaccines offered by the Vaccine for Children program in 2003 and was made part of the universal recommendations for the coming season.

The rationale for the new universal recommendation is the high rate of influenza-related hospitalizations among those aged 6 to 23 months, which varies from year to year and has been documented to be as high as 5/1000.<sup>3,4</sup> While hospitalization rates are higher for infants aged 0 to 5 months, influenza vaccine is not approved for use in this age group.

Death from influenza in infants and children is not common. However, in the 2003 to 2004 influenza season, 58 influenza deaths among those aged <2 years were recorded.<sup>1</sup> Added benefits from vaccinating infants and children may include decreased rates of otitis media.<sup>5,6</sup>

## ■ PRACTICAL ASPECTS OF VACCINE ADMINISTRATION

Some of the most important practical details involved with immunizing 6- to 23-month-olds include the following:

- The age group includes those who have completed 6 months of life (are now in their 7th month) up to the second birthday. Influenza vaccine is 65% to 90% effective in this age group.

Correspondence: 12229 S. Chinook, Phoenix, AZ 85044.  
E-mail: dougco@u.arizona.edu.

- The dose of influenza vaccine for infants and children up to their 3rd birthday is 0.25 mL.
- The vaccine should be administered intramuscularly in the anterolateral thigh with a 1-inch needle.
- Two doses, 1 month apart, are recommended for infants or children aged <9 years receiving influenza vaccine for the first time. (Dose recommendations for all age groups are listed in **Table 1**.)
- Only 1 vaccine product has been approved for those younger than 4 years: FluZone, produced by Aventis Pasteur.
- The vaccine is made with killed virus and can be given simultaneously with other recommended vaccines.
- The live attenuated influenza vaccine, administered intranasally, is not approved for children before their 5th birthday.
- The vaccine should be stored at 2° to 8°C (35° to 46°F) and should not be frozen.
- Vaccine left over from last year should not be used this year.
- Contraindications to influenza vaccine are listed in **Table 2**.

### The thimerosal controversy

Family physicians are likely to encounter questions from parents or guardians about thimerosal in influenza vaccines. Thimerosal is a preservative containing mercury, which has been used in vaccines for more than 70 years. Because of the increasing number of recommended childhood vaccines and the resulting cumulative exposure to mercury, there has been a concerted effort since 1999 to reduce the content of thimerosal in vaccine products.

Almost all vaccines are now free of thimerosal. However, inactivated influenza vaccine distributed in multidose vials does contain thimerosal, 12.5 µg mercury/0.25 mL dose. Single-dose vials containing inactivated influenza vaccine do not contain thimerosal as a preservative, but this product still contains trace amounts of mercury, <0.5 µg/0.25 mL dose.

**TABLE 1**

### Inactivated influenza vaccine\* dosage, by age group

Age group†	Dose	No of doses	Route‡
6–35 mo	0.25 mL	1 or 2§	Intramuscular
3–8 y	0.50 mL	1 or 2§	Intramuscular
9 y	0.50 mL	1	Intramuscular

\*A 0.5-mL dose contains 15 mg each of A/Fujian/411/2002 (H3H2)-like, A/New Caledonia/20/99 (H1N1)-like, and B/Shanghai/361/2002-like antigens. For the A/Fujian/411/2002 (H3H2)-like antigen, manufacturers may use the antigenically equivalent A/Wyoming/3/2003 (H3N2) virus, and for the B/Shanghai/361/2002-like antigen, manufacturers may use the antigenically equivalent B/Jilin/20/2003 virus or B/Jiangsu/10/2003 virus. Manufacturers include Aventis Pasteur, Inc (FluZone® split virus), and Chiron (Fluvirin™ purified surface antigen vaccine). FluZone is approved by the Food and Drug Administration for use among persons aged ≥6 months. Fluvirin is approved for use among persons aged ≥4 months. For further product information, call Aventis Pasteur at 800-822-2463 or Chiron at 800-200-4278.

† Because of their decreased potential for causing febrile reactions, only split-virus vaccines should be used for children aged <13 years. Whole-virus vaccine is not available in the United States. Split-virus vaccine might be labeled as *split*, *subvirion*, or *purified surface antigen* vaccine. Immunogenicity and side effects of split- and whole-virus vaccines are similar among adult when vaccines are administered in the recommended dosage.

‡ For adults and older children, the recommended site of vaccination is the deltoid muscle. The preferred site for infants and young children is the anterolateral aspect of the thigh.

§ Two doses administered at least 1 month apart are recommended for children aged <9 years who are receiving influenza vaccine for the first time.

Source: Harper et al 2004.<sup>1</sup>

No evidence has shown conclusively that mercury-containing vaccines cause serious adverse effects. A recent Institute of Medicine report concludes that the weight of evidence supports a lack of causation between thimerosal and autism.<sup>7</sup> Nevertheless, many parents remain concerned about mercury exposure from vaccines. Reassure those who are concerned that the cumulative exposure to mercury from

TABLE 2

<b>Contraindications to influenza vaccine</b>
• Those who have severe allergy (anaphylactic hypersensitivity) to chicken eggs
• Those who have had a severe reaction to an influenza vaccination
• Those who developed Guillain-Barré syndrome within 6 weeks of receiving an influenza vaccine
• Children aged <6 months
• Those with an acute febrile illness (vaccine may be given once symptoms have disappeared)

all vaccines has decreased markedly and that influenza vaccine contains only low amounts of thimerosal. Those wishing to decrease this risk even further should be given the option of the single-dose vial product, if available.

### Timing vaccination for optimal protection

The influenza season varies year to year but normally occurs between November and March. Vaccination for those at high risk of influenza complications, including those aged 6 to 23 months, should begin in September and October. Those who need 2 doses should receive the second by December if possible.

Because of the length of the influenza season and the fact that the inactivated influenza vaccine is not approved for use during the first 6 months of life, infants will become eligible for the vaccine at different points in the influenza season. Office procedures should be implemented to identify eligible infants as the season progresses and to notify parents or guardians of the opportunity to vaccinate their infant.

If an infant enters the 7th month of life late in the influenza season and vaccine is still available, vaccination should still be considered, not only to offer protection in the current year but

also to reduce the number of doses needed the next year. In instances when only 1 dose of a recommended 2-dose schedule is completed, only 1 dose is needed the following year.

### Vaccinate close contacts of infants and children

The new ACIP recommendations state that persons who can transmit influenza to those at high risk of complications should also be vaccinated. This includes household contacts of, and those who provide care to, children aged <2 years.

For infants in their first 6 months of life, preventing infection among close contacts is the major preventive intervention available. The Vaccine for Children program now includes influenza vaccine for members of households (those who are aged <18 years) where children aged <2 years live.

### Vaccine complications and contraindications

Local reactions including redness, pain, and swelling are common after influenza vaccine administration. Generalized reactions including fever, malaise, and myalgia are less common and can start within 6 to 12 hours and last 1 to 2 days. Contraindications to vaccine administration are few (Table 2).

### When chemoprophylaxis is an option

Only 2 options exist for chemoprophylaxis against influenza in children before their 13th birthday: amantadine and rimantadine. The dosage for each is 5 mg/kg/d, up to 150 mg, in 1 or 2 doses. Both are effective only against influenza A and are approved for use only after the 1st birthday. Still, this option should be kept in mind for unvaccinated children who are exposed to influenza.

A chemoprophylactic agent can be started at the same time the vaccine is administered. Since it takes 2 weeks to develop protective levels of antibodies, chemoprophylaxis should

### Update: Anticipated shortage of vaccine in fall of 2004

In early October, 1 of the 2 producers of inactivated influenza vaccine for the United States market, Chiron Corporation, had its license suspended by the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom, where their plant is located. This will cause a shortage of vaccine, since Chiron was to have supplied about half of the 100 million doses planned for this country.

Chiron, however, was not a producer of vaccine for children aged <4 years. Based on this anticipated shortfall, the ACIP is recommending that the vaccine be given preferentially to those at high risk for influenza complications (**Table 3**) and that those who are not in one of these categories forgo vaccination. Physicians who will not have an adequate supply of vaccine for their patient population are encouraged to have their priority patients seek vaccine at another location.

**TABLE 3**

### Priority groups for influenza vaccination

The following priority groups for vaccination with inactivated influenza vaccine this season are considered to be of equal importance.

- All children aged 6 to 23 months
- Adults aged 65 years and older
- Persons aged 2 to 64 years with underlying chronic medical conditions
- All women who will be pregnant during the influenza season
- Residents of nursing homes and long-term care facilities
- Children aged 6 months to 18 years on chronic aspirin therapy
- Health-care workers involved in direct patient care
- Out-of-home caregivers and household contacts of children aged <6 months.

be continued for 2 weeks with those who need only 1 vaccine, and until 2 weeks after the 2nd vaccine for those who need 2 doses.

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