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Date: August 28, 2009

To: Physicians
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From: Jeffrey P. Davis, MD
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Jay A. Gold, MD, JD, MPH
Wisconsin Adult Immunization Coalition *JAGold*

Jeffrey P. Davis MD
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Re: 2009-2010 Recommendations for Use of **Seasonal Influenza** Vaccines

The 2009 Advisory Committee on Immunization Practices (ACIP) recommendations for the prevention and control of seasonal influenza with vaccines were formally issued on July 31, 2009 and include a listing of the groups recommended to be immunized this year. This document can be downloaded from the MMWR website at www.cdc.gov/mmwr. Updated ACIP information on the vaccine supply and timing of distribution of influenza vaccine that affect the target groups will be posted on the Centers for Disease Control and Prevention (CDC) website at www.cdc.gov/flu as needed. The 2009-10 Vaccine Information Statements (VIS) for Influenza are available at www.cdc.gov/vaccines/pubs/vis/default.htm.

For the 2009-10 influenza season we recommend that as soon as seasonal influenza vaccines are available you begin to immunize individuals against seasonal influenza to avoid conflicts with clinics that are expected to be conducted in mid- to late October to administer novel influenza A (H1N1) vaccines. **Seasonal influenza vaccines are not expected to provide substantial protection against infection with the recently identified novel influenza A (H1N1) virus and guidance for prevention of infection against this virus will be published separately.**

It is important that you be aware of the current recommendations and periodically visit the CDC website for additional information and updates. Access to updated or supplemental information is often necessary throughout the influenza season and the months leading up to it. CDC and other public health agencies will assess the vaccine supply on a continuing basis throughout the manufacturing period and will inform both providers and the general public in the event of substantial delays or inadequate supply.

Four companies will produce seasonal trivalent inactivated influenza vaccine (TIV) during the 2009-10 influenza season. The names of the companies and the vaccine they produce are: sanofi pasteur (FluZone[®]), Novartis Vaccine, formerly Chiron (Fluvirin[™]), GlaxoSmithKline (Fluarix[™] and FluLaval[™]) and CSL Biotherapies (Afluria[®]). One company, MedImmune, Inc., will manufacture the live, attenuated seasonal influenza vaccine (LAIV) FluMist[™] for the U. S. market.

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FluZone[®] (manufactured by sanofi pasteur) is approved for use in persons ≥ 6 months old including those with high-risk conditions. Fluvirin[™] (manufactured by Novartis) is labeled in the United States for use in persons ≥ 4 years old, Fluarix[™] and FluLuval[™] (both manufactured by GlaxoSmithKline) and Afluria[®] (manufactured by CLS Biotherapies) are labeled for use in persons ≥ 18 years old including those with high-risk conditions. FluMist[™] (manufactured by MedImmune, Inc.) is approved for use among healthy, nonpregnant persons 2-49 years old.

Currently we do not expect vaccine related delays or shortages, but we recognize the fragile nature of influenza vaccine production and distribution. In the event of a shortfall in production or a delay in the delivery of adequate supplies of vaccine, you will be notified of any prioritization of high-risk groups. If such an event should occur a Prioritization Plan will be distributed. If needed, this Plan will provide a sequence of priority groups for you to follow to assure that high-risk individuals receive influenza vaccine first. Because the annual supply and timing of distribution of influenza vaccine cannot be guaranteed, we continue to stress the importance of local partnerships. The recent history of vaccine delivery delays and shortages underscores the need for these local coalitions to help coordinate redistribution and use of influenza vaccine.

The 2009-10 ACIP recommendations include three principle changes or updates:

1. Annual vaccination of all children aged 6 months-18 years should begin as soon as the 2009-10 influenza vaccine is available. Annual vaccination of all children aged 6 months-4 years (59 months) and older children with conditions that place them at increased risk for complications from influenza should continue to be a primary focus of vaccination efforts as providers and programs transition to routinely vaccinating all children.
2. The composition of the 2009-10 trivalent vaccine includes the following three virus strains: A/Brisbane/59/2007 (H1N1)-like, A/Brisbane/10/2007 (H3N2)-like and B/Brisbane/60/2008-like antigens. The TIV and LAIV vaccines will contain these three antigens.
3. Most seasonal influenza A (H1N1) virus strains tested from the United States and other countries are now resistant to oseltamivir. Updated guidance on antiviral use will be available before the start of the 2009-2010 influenza season.

Additional points to emphasize:

- It is important to administer 2 doses of seasonal influenza vaccine to all children aged 6 months-8 years who have not been vaccinated previously at any time with either LAIV or TIV.
- Children 6 months-8 years who received only 1 dose in their first year of vaccination should receive 2 doses the following year.
- It is important to continue to offer seasonal influenza vaccine throughout the influenza season and schedule immunization clinics throughout the influenza season to include December and later.
- FluMist is now shipped to the end user at a temperature of 35°F-46°F (2°C-8°C). FluMist should be stored at 35°F-46°F (2°C-8°C) upon receipt and should remain at that temperature until the expiration date is reached. Do not freeze FluMist. The dose of FluMist[™] is 0.2 mL, divided equally between each nostril.
- Vaccine Information Statements (VISs) have been published by the CDC for the seasonal influenza vaccines. Two separate forms are available, one for LAIV and one for TIV and can be downloaded from the CDC website at: <http://www.cdc.gov/vaccines/pubs/vis/default.htm>. Separate VISs for the novel H1N1 vaccines will be published at a later date.
- Providers are encouraged to administer seasonal influenza vaccine as soon as available. This will help alleviate some of the increased demand later on in the season. Concerns about giving the vaccine too early to provide protection through the entire season are unfounded, as no compelling evidence has been shown for a more rapid decline of influenza vaccine-induced antibody response in the elderly, compared to young adults¹.

¹ Skowronski DM, Tweed SA, De Serres G. JID 2008; 197:490-502

Childhood influenza vaccination issues and recommendations

In July 2004, influenza vaccine was added to the routine childhood immunization schedule. Recommendations now include influenza vaccination of all children aged 6 months-18 years because children and adolescents are at greater risk for influenza complications and are important spreaders of influenza virus in the community.

When immunizing children several factors must be considered or reemphasized:

- Either TIV or LAIV can be used when vaccinating healthy, nonpregnant persons aged 2-49 years. Children aged 6 months-8 years who have not received vaccination against influenza previously should receive 2 doses of influenza vaccine (doses separated by ≥ 4 weeks) during the first season they are vaccinated. Administer 2 doses (separated by at least 4 weeks) to children younger than age 9 years who are receiving influenza vaccine for the first time or were vaccinated for the first time during the previous influenza season but only received 1 dose.
- Vaccination of children younger than age 9 years who are receiving seasonal influenza vaccine for the first time can begin as soon as vaccine becomes available. This practice increases the opportunity for both doses to be administered in the same influenza vaccination season and before the onset of influenza activity.
- Children aged 6-35 months should only receive a 0.25 mL dose of a split-virus vaccine formulation. Currently only sanofi pasteur provides this vaccine.
- Fluvirin™ (Novartis) is approved only for persons aged ≥ 4 years and Fluarix™ and FluLuval™ (GlaxoSmithKline) and Afluria® (CSL Biotherapies) are labeled for use in persons aged ≥ 18 years. FluMist™ (MedImmune Inc.) is approved for healthy, non-pregnant individuals aged 2-49 years.
- Influenza vaccine without thimerosal used as a preservative will be available in limited supply for the 2009-10 influenza season. The supply of this vaccine will be increased as manufacturing capabilities are expanded. Elimination of thimerosal in other vaccines has already been achieved and has resulted in substantially lowered cumulative exposure to thimerosal. The ACIP states that persons for whom inactivated vaccine is recommended may receive any age and risk factor appropriate vaccine preparation, depending on availability.
- The first and second doses of vaccine do not have to match; TIV or LAIV can be used to complete the two dose requirement. Doses should be separated by at least 4 weeks.

If you have any questions please call the Regional Immunization Program Advisor in your area listed below.

Please share this memo with other interested parties.

Immunization Program Advisors:

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