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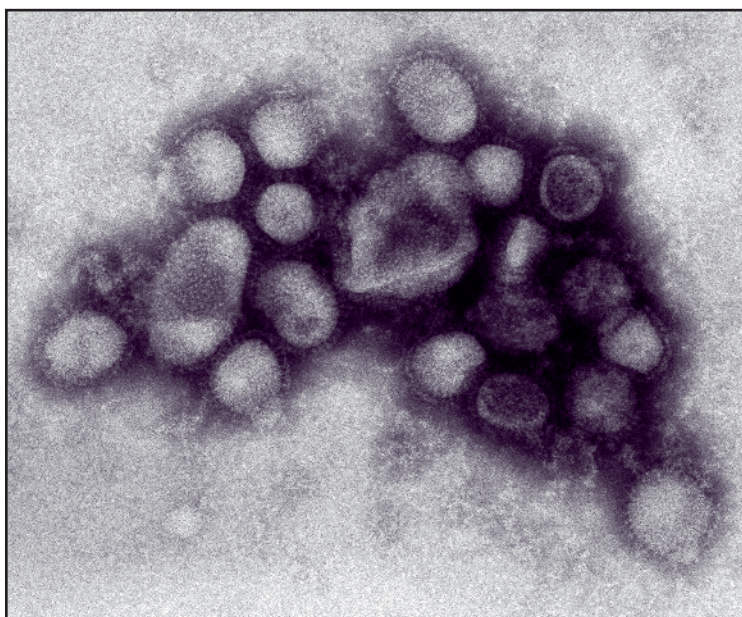
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Recommendations and Reports

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Use of Influenza A (H1N1) 2009 Monovalent Vaccine

**Recommendations of the Advisory Committee
on Immunization Practices (ACIP), 2009**



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On the cover: An electron micrograph of the novel influenza A (H1N1) virus.

Use of Influenza A (H1N1) 2009 Monovalent Vaccine

Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009

Prepared by
National Center for Immunization and Respiratory Diseases, CDC

Summary

This report provides recommendations by CDC's Advisory Committee on Immunization Practices (ACIP) regarding the use of vaccine against infection with novel influenza A (H1N1) virus. Information on vaccination for seasonal influenza has been published previously (CDC. Prevention and control of seasonal influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices [ACIP], 2009. MMWR 2009;58[No. RR-8]). Vaccines against novel influenza A (H1N1) virus infection have not yet been licensed; however, licensed vaccine is expected to be available by mid-October 2009. On July 29, 2009, ACIP reviewed epidemiologic and clinical data to determine which population groups should be targeted initially for vaccination. ACIP also considered the projected vaccine supply likely to be available when vaccine is first available and the expected increase in vaccine availability during the following 6 months. These recommendations are intended to provide vaccination programs and providers with information to assist in planning and to alert providers and the public about target groups comprising an estimated 159 million persons who are recommended to be first to receive influenza A (H1N1) 2009 monovalent vaccine. The guiding principle of these recommendations is to vaccinate as many persons as possible as quickly as possible. Vaccination efforts should begin as soon as vaccine is available. State and local health officials and vaccination providers should make decisions about vaccine administration and distribution in accordance with state and local conditions. Highlights of these recommendations include 1) the identification of five initial target groups for vaccination efforts (pregnant women, persons who live with or provide care for infants aged <6 months, health-care and emergency medical services personnel, children and young adults aged 6 months–24 years, and persons aged 25–64 years who have medical conditions that put them at higher risk for influenza-related complications), 2) establishment of priority for a subset of persons within the initial target groups in the event that initial vaccine availability is unable to meet demand, and 3) guidance on use of vaccine in other adult population groups as vaccine availability increases. Vaccination and health-care providers should be alert to announcements and additional information from state and local health departments and CDC concerning vaccination against novel influenza A (H1N1) virus infection. Additional information is available from state and local health departments and from CDC's influenza website (<http://www.cdc.gov/flu>).

Introduction

In April 2009, a new influenza A (H1N1) virus, novel influenza A (H1N1) virus, was determined to be the cause of influenza illness in two children in the United States during March and April 2009 (1,2) and the cause of outbreaks of respiratory illness in Mexico (3). This virus was transmitted in communities across North America within weeks and was identified in many areas of the world by May 2009 (4,5). On June 11, 2009, the World Health Organization (WHO) declared a worldwide pandemic, indicating uncontained community-level transmission of the novel influenza A (H1N1)

virus in multiple areas of the world (5). Worldwide transmission of the novel influenza A (H1N1) virus has continued since June in both the Northern and Southern Hemispheres (6). Transmission is likely to persist and might increase in the Northern Hemisphere during fall and winter. In contrast to seasonal influenza, current evidence indicates that relatively few severe cases of novel influenza A (H1N1) virus infection have occurred among older persons, and the highest hospitalization rates for illness caused by this virus have been among persons aged <65 years (7). The signs and symptoms of novel influenza A (H1N1) virus infection are similar to those of seasonal influenza, and specific diagnostic testing is required to distinguish novel influenza A (H1N1) virus from seasonal influenza virus (7; CDC, unpublished data, 2009).

Influenza vaccination is the most effective method for preventing influenza and influenza-related complications. However, current seasonal influenza vaccines are not likely to provide protection against novel influenza A (H1N1) virus (8).

The material in this report originated in the National Center for Immunization and Respiratory Diseases, Anne Schuchat, MD, Director.

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Specific vaccines against the novel influenza A (H1N1) virus are being manufactured, and licensed vaccine is expected to be available in the United States by mid-October 2009 (9). However, the initial supply of these vaccines might not be enough to meet the demand for vaccine. For this reason, CDC's Advisory Committee on Immunization Practices (ACIP) recommends that certain groups at highest risk for infection or influenza-related complications should be the initial targets for vaccination. Highlights of these recommendations include 1) the identification of five initial target groups for vaccination efforts (pregnant women, persons who live with or provide care for infants aged <6 months, health-care and emergency medical services personnel, children and young adults aged 6 months–24 years, and persons aged 25–64 years who have medical conditions that put them at higher risk for influenza-related complications), 2) establishment of priority for a subset of persons within the initial target groups in the event that initial vaccine availability is unable to meet demand, and 3) guidance on use of vaccine in other adult population groups as vaccine availability increases. Because novel influenza A (H1N1) virus is continuing to cause illness in the United States and worldwide, the primary focus of vaccination efforts should be to vaccinate as many persons as possible in the recommended target groups as quickly as possible once vaccine becomes available. As vaccine availability increases, additional groups are recommended for vaccination. ACIP will review new epidemiologic and clinical data as they become available and might revise these recommendations.

Methods

ACIP provides recommendations to CDC for the prevention and control of vaccine-preventable diseases in the U.S. civilian population. During April–July 2009, the ACIP Influenza Working Group met frequently by teleconference to discuss new information on the spread of novel influenza A (H1N1) virus. In the process of developing vaccination recommendations for consideration by the full ACIP, members considered the evolving burden of illness caused by the virus, the age and risk groups most affected, progress in developing vaccines, anticipated vaccine supply, and various possible vaccination strategies. ACIP's deliberations were informed by consultation with other federal agencies and a review of vaccine allocation guidance developed as part of influenza prepandemic planning during 2007–2008 (10).

The full committee's initial discussions related to novel influenza A (H1N1) virus took place during a public ACIP session held on June 25–26, 2009. At a subsequent public meeting held on July 29, 2009, ACIP made recommendations for use of the influenza A (H1N1) 2009 monovalent vaccine currently

in production for the U.S. market. Information presented at these meetings is available at <http://www.cdc.gov/vaccines/recs/acip/slides-jun09.htm> and <http://www.cdc.gov/vaccines/recs/acip/slides-july09-flu.htm>.

Background

Human infections with the novel influenza A (H1N1) virus were first identified in April 2009 (1), and infections with this virus have been reported worldwide (5). Because serologic studies suggest that a large majority of the population is susceptible to novel influenza A (H1N1) virus, substantial potential exists for widespread infection (2). The novel influenza A (H1N1) virus is antigenically and genetically distinct from other human influenza A (H1N1) viruses in circulation since 1977 (2). As of August 1, 2009, the novel influenza A (H1N1) viruses circulating worldwide appear to be antigenically similar (11).

Clinical Features

The signs and symptoms of novel influenza A (H1N1) virus infection are similar to those of seasonal influenza (7,12). Definitive diagnosis of novel influenza A (H1N1) virus infection requires specific testing for H1N1 viruses using real-time reverse transcriptase–polymerase chain reaction or viral culture (7,13). Rapid influenza diagnostic tests (RIDTs) for seasonal influenza sometimes can detect novel influenza A (H1N1) virus, but sensitivity has been estimated at 40%–70% (13,14). Negative RIDTs should not be used to exclude the diagnosis of novel influenza A (H1N1) virus infection (13).

The age distribution of confirmed illness, severity of illness, and prevalence of medical risk factors among persons with severe illness have been consistent among many countries and over time. As of July 31, 2009, the median age of persons with laboratory-confirmed infections in the United States was 12 years, and the highest infection incidence was among persons aged 5–24 years (7,11). The incidence of infection was lowest among persons aged ≥65 years. Similar findings have been reported in other countries (15).

A comparison of the age distribution of hospitalized persons with laboratory-confirmed novel influenza A (H1N1) also demonstrates a striking difference from seasonal influenza (Figure). As of July 31, 2009, the median age of hospitalized persons with laboratory-confirmed novel influenza A (H1N1) virus infection was 20 years, and the incidence of hospitalization was highest among young children aged <4 years (11; CDC, unpublished data, 2009). Only 282 (5%) of 5,514 hospitalizations and 29 (8%) of the 353 reported deaths had occurred among persons aged ≥65 years (CDC, unpublished data, 2009). The median age among persons who died with

