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TO: H1N1 Influenza Community Partners

FROM: William D. Hacker, MD, FAAP, CPE
Commissioner

SUBJECT: Fall 2009 H1N1 Influenza Clinician Toolkit

DATE: October 5, 2009

Thank you for agreeing to collaborate with Kentucky's public health partners to provide the H1N1 influenza vaccine in your area. On June 11, 2009, the World Health Organization (WHO) declared a worldwide pandemic, indicating local transmission of the novel influenza A (H1N1) virus in multiple areas of the world. To minimize the adverse health outcomes of this virus in our state, the Kentucky Department for Public Health advocates a multi-pronged approach: 1) H1N1 influenza vaccine administration to targeted populations identified by the Centers for Disease Control and Prevention (CDC), 2) the appropriate use of antiviral medications, and 3) individual and community mitigation strategies, such as handwashing and social distancing.

The Fall 2009 H1N1 Influenza Clinician Toolkit provides a comprehensive clinician's guide to address the issues surrounding the pandemic, including the most recent CDC literature regarding the H1N1 influenza virus, sample protocols, clinical information regarding the vaccine, vaccine administration, antivirals, and patient education materials. Also included are community mitigation resources, infection control policies, useful H1N1 influenza websites, and a Frequently Asked Questions (FAQ) list.

This information is also located at: http://healthalerts.ky.gov/Pages/HealthProfessionals.aspx.
Any new or updated information will be added to the toolkit link on this site. It is our hope this toolkit provides you and your staff with valuable resources and reference materials that will help you to provide the best possible care to your patients during this influenza season.

Thank you again for your willingness to participate in Kentucky's response to the H1N1 influenza pandemic.

MMWR™
Morbidity and Mortality Weekly Report
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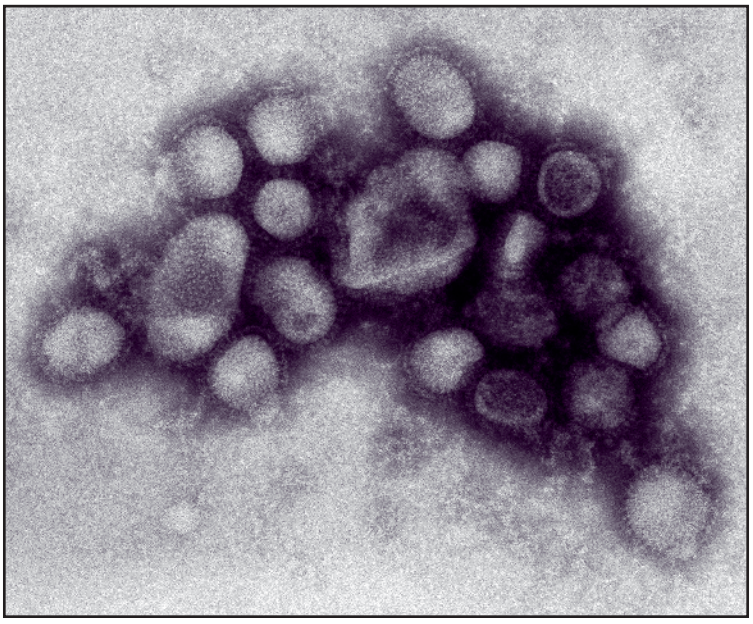
Recommendations and Reports | August 28, 2009 / Vol. 58 / No. RR-10

Use of Influenza A (H1N1) 2009 Monovalent Vaccine

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



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

The *MMWR* series of publications is published by the Coordinating Center for Health Information and Service, Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, Atlanta, GA 30333.

Suggested Citation: Centers for Disease Control and Prevention. [Title]. MMWR 2009;58(No. RR-#):[inclusive page numbers].

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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*).

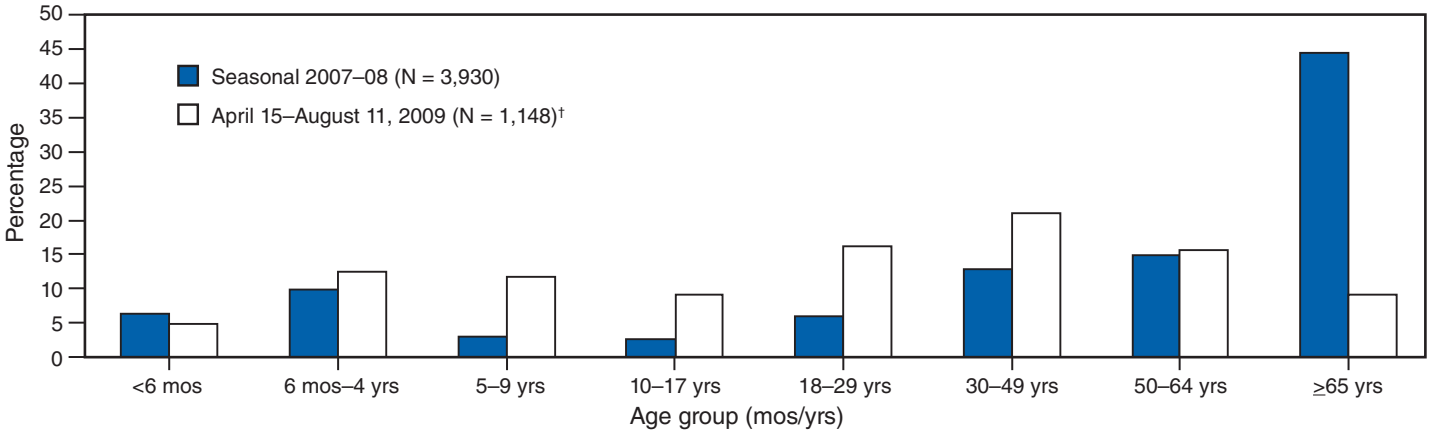
Clinical Features

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

FIGURE. Distribution by age group of persons hospitalized with laboratory-confirmed influenza,* — United States, 2007–08 winter influenza season and April 15–August 11, 2009



Source: Emerging Infections Program, CDC.

* Evidence of a positive influenza test result by viral culture, direct fluorescent assay, immunoflourescence assay, real-time reverse–transcription polymerase chain reaction, rapid influenza diagnostic test, serology, or written note in the medical chart.

† Influenza subtype cannot be determined with some types of tests, and the proportion of positive influenza tests that were attributable to novel influenza A (H1N1) virus cannot be determined. However, national surveillance for influenza viruses indicates that >95% of viruses circulating during this time were novel influenza A (H1N1) virus.

novel influenza A (H1N1) virus infection was 37 years. In contrast, in multiple studies of seasonal influenza, hospitalization and mortality rates have been highest among persons aged ≥65 years, and an estimated 90% of seasonal influenza-related deaths and 60% of seasonal influenza-related hospitalizations occurred among adults aged ≥65 years (*16,17*). As of July 31, 2009, only 282 (5%) of 5,514 hospitalizations and 29 (8%) of the 353 reported deaths attributed to novel influenza A (H1N1) virus infection had occurred among persons aged ≥65 years (CDC, unpublished data, 2009). Cumulative novel influenza A (H1N1) hospitalization rates for April–July 2009 approached or exceeded typical end-of-season cumulative rates for seasonal influenza among school-aged children and adults aged 18–49 years in the Emerging Infections Program* (EIP) surveillance areas (*11*). However, among persons aged ≥65 years, these cumulative hospitalization rates are <20% of the rates typically observed during the winter among persons in this age group. The median age of hospitalized patients during the 2007–08 influenza season in EIP surveillance areas was 59 years, compared with a median age of 26 years for persons hospitalized in these areas during April–July 2009 (CDC, unpublished data, 2009). In addition, outbreaks attributable to novel influenza A (H1N1) viruses among older adults in long-term–care facilities have not been reported even when novel influenza A (H1N1) has been identified among healthcare workers in these facilities who worked while ill.

Medical risk factors for severe infection are similar to those identified previously in studies of seasonal influenza (*12*). In one case series of 179 patients hospitalized with laboratory-confirmed novel influenza A (H1N1) virus infection, 117 (65%) patients had a medical risk factor previously associated with severe infection in studies of seasonal influenza (e.g., chronic heart, lung, renal, liver disease; cancer or immunosuppression; or pregnancy) (*12,18*; CDC, unpublished data, 2009). Deaths caused by novel influenza A (H1N1) have been reported among pregnant women. In one case series, the incidence of hospitalization for confirmed novel influenza A (H1N1) virus infection among pregnant women was four times higher than that of the general population (*19*). Obesity (defined as body-mass index [BMI] ≥30) or morbid obesity (BMI ≥40) has been noted among hospitalized patients in some case series (*20,21*). However, the majority of these patients had other medical risk factors, and investigations to determine whether obesity or morbid obesity is an independent risk factor for severe infection are underway.

* CDC's Emerging Infections Program Influenza Project conducts surveillance for laboratory-confirmed, influenza-related hospitalizations in children (persons aged <18 years) and adults in 60 counties covering 12 metropolitan areas of 10 states (San Francisco, California; Denver, Colorado; New Haven, Connecticut; Atlanta, Georgia; Baltimore, Maryland; Minneapolis/St. Paul, Minnesota; Albuquerque, New Mexico; Las Cruces, New Mexico; Albany, New York; Rochester, New York; Portland, Oregon; and Nashville, Tennessee). Cases are identified by reviewing hospital laboratory and admission databases and infection-control logs for children and adults with a documented positive influenza test (viral culture, direct/indirect fluorescent antibody assay (DFA/IFA), real-time reverse transcription–polymerase chain reaction (rRT-PCR), or a commercial rapid antigen test) conducted as a part of routine patient care.

Epidemiology and Transmission

The epidemiology of novel influenza A (H1N1) virus infection is under investigation, and epidemiologic characteristics might change as transmission continues. Outbreaks in settings in which young persons congregate (e.g., schools, colleges, and camps) have been a frequent source of community transmission (*22,23*). During spring and summer 2009, many schools and camps in the United States were dismissed temporarily as a result of outbreak concerns, causing considerable community impact (*24*).

The number of laboratory-confirmed infections underestimates the incidence of influenza illness caused by novel influenza A (H1N1) virus infection because laboratory testing has been focused on persons with more severe infection. Similar to clinical practice for seasonal influenza, many healthy persons with likely novel influenza A (H1N1) virus infections never are tested because their illness does not require medical intervention or specific diagnosis. Community surveys and population-based telephone surveys in areas with focal outbreaks of novel influenza A (H1N1) virus infection have identified self-reported influenza-like illness (ILI) among approximately 6% of the population in the areas surveyed (CDC, unpublished data, 2009). In June 2009, the New York City Health Department conducted a household survey that indicated that 7% of New Yorkers reported having ILI (fever accompanied by either cough or sore throat) during May 1–20, 2009; because other indicators of ILI (e.g., physician visits for respiratory illness) demonstrated continued and increasing community transmission within New York City, subsequent surveys are likely to indicate that even higher rates of self-reported ILI occurred during late May–June 2009 (*25*).

Transmission of novel influenza A (H1N1) virus infection in health-care settings has been reported. Among 11 health-care personnel (HCP) with probable or possible patient-to-HCP acquisition and available information on personal protective equipment use, only three HCP reported always using either a surgical mask or an N95 respirator in one case series (*26*). Acquisition of novel influenza A (H1N1) virus infection by HCP in community settings also has been identified, raising the possibility of introduction of novel influenza A (H1N1) viruses to patients in health-care settings by infected HCP (*26*).

Vaccination Against Novel Influenza A (H1N1) Virus Infection

Limited data from serologic studies of persons who received vaccination with seasonal influenza vaccines suggest that seasonal influenza vaccines will not provide protection against novel influenza A (H1N1) virus. Among adults, cross-reactive antibody to novel influenza A (H1N1) virus at titers that correlate with protection from illness in studies of seasonal influenza vaccine was detected in 6%–9% of those aged 18–64 years and in 33% of those aged >60 years. No children tested had cross-reactive antibody to novel influenza A (H1N1) virus. Titers of cross-reactive antibody to novel influenza A (H1N1) virus did not increase after administration of seasonal influenza vaccine (*2,8*).

Vaccines against novel influenza A (H1N1) virus infection are being produced using methods similar to those used for seasonal influenza vaccines. Licensure of vaccines against novel influenza A (H1N1) virus will be based on the same licensure standards used for seasonal influenza vaccines, as is done routinely each year when strains are changed in the seasonal vaccine. Both live, attenuated and inactivated influenza A (H1N1) 2009 monovalent vaccine formulations will be available initially; as with seasonal influenza vaccines, neither of these vaccines will contain adjuvants. The Food and Drug Administration (FDA) and WHO have selected A/California/07/2009 (H1N1) for use as the strain for the vaccines currently being manufactured.

In previously unvaccinated persons aged <9 years, 2 doses of seasonal influenza vaccine are required to induce immunity because young children typically have had limited exposure to influenza viruses and are not immunologically primed (i.e., they do not have preexisting antibodies) (*12*). The lack of preexisting antibody cross-reactive with the novel influenza A (H1N1) virus among children and younger adults raises the possibility that 2 doses of vaccine (typically separated by ≥21 days) also will be needed to provide protection for persons in these age groups. Ongoing studies will provide additional information about the immune response vaccine, including which groups might need 2 doses. Updated information will be published by CDC in *MMWR* or will be available at http://www.cdc.gov/flu.

Several vaccines containing an adjuvant also are being studied but probably will not be available initially. These vaccines likely will need to be used under an Emergency Use Authorization.[†] Additional guidance will be provided if adjuvanted vaccines are made available.

[†] If an emerging public health threat is identified for which no licensed or approved product exists, the Project BioShield Act of 2004 authorizes the Food and Drug Administration commissioner to issue and Emergency Use Authorization so promising countermeasures can be disseminated quickly to protect the safety of the U.S. population.

Recommended Use of Influenza A (H1N1) 2009 Monovalent Vaccine

ACIP recommends that vaccination efforts should focus initially on persons in five target groups (Box) whose members are at higher risk for influenza or influenza-related complications, are likely to come in contact with influenza viruses as part of their occupation and could transmit influenza viruses to others in medical care settings, or are close contacts of infants aged <6 months (who are too young to be vaccinated). In the event that vaccine availability is unable to meet initial demand, priority should be given to a subset of the five target groups (Box).

Initial Target Groups

When vaccine is first available, ACIP recommends that programs and providers administer vaccine to persons in the following five target groups (order of target groups does not indicate priority):

- pregnant women,
- persons who live with or provide care for infants aged <6 months (e.g., parents, siblings, and daycare providers),
- health-care and emergency medical services personnel,[§]
- persons 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.[¶]

These five target groups comprise an estimated 159 million persons in the United States. This estimate does not accurately account for persons who might be included in more than one category (e.g., a health-care worker with a high-risk condition).

[§] Health-care personnel (HCP) include all paid and unpaid persons working in health-care settings who have the potential for exposure to patients with influenza, infectious materials, including body substances, contaminated medical supplies and equipment, or contaminated environmental surfaces. HCP might include (but are not limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the health-care facility, and persons (e.g., clerical, dietary, housekeeping, maintenance, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCP. The recommendations in this report apply to HCP in acute-care hospitals, nursing homes, skilled nursing facilities, physicians' offices, urgent care centers, and outpatient clinics, and to persons who provide home health care and emergency medical services (*27*). Emergency medical services personnel might include persons in an occupation (e.g., emergency medical technicians and fire fighters) who provide emergency medical care as part of their normal job duties.

[¶] Chronic medical conditions that confer a higher risk for influenza-related complications include chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, cognitive, neurologic/neuromuscular, hematologic, or metabolic disorders (including diabetes mellitus) or immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus) (*12*).

Vaccination programs and providers should begin vaccination of persons in all these groups as soon as vaccine is available.

Subset of Target Groups During Limited Vaccine Availability

Current projections of initial vaccine supply indicate that establishment of a subset of the five initial target groups will not be necessary in most areas. However, demand for vaccination and initial supply might vary considerably across geographic areas. If the supply of the vaccine initially available is not adequate to meet demand for vaccination among the five target groups listed above, ACIP recommends that the following subset of the initial target groups receive priority for vaccination until vaccine availability increases (order of target groups does not indicate priority):

- pregnant women,
- persons who live with or provide care for infants aged <6 months (e.g., parents, siblings, and daycare providers),
- health-care and emergency medical services personnel who have direct contact with patients or infectious material,
- children aged 6 months–4 years, and
- children and adolescents aged 5–18 years who have medical conditions that put them at higher risk for influenza-related complications.

This subset of the five target groups comprises approximately 42 million persons in the United States. Vaccination programs and providers should give priority to this subset of the five target groups only if vaccine availability is too limited to initiate vaccination for all persons in the five initial target groups.

Expanding Vaccination Efforts Beyond Initial Target Groups

Decisions about expanding vaccination to include additional populations beyond the five initial target groups should be made at the local level because vaccine availability and demand might vary considerably by area. Once vaccination programs and providers are meeting the demand for vaccine among the persons in the five initial target groups, vaccination should be expanded to all persons aged 25–64 years. Decisions about expanding or establishing priorities for vaccination should be made in accordance with local circumstances based on the judgment of state and local health officials and health-care providers. CDC and other public health agencies will assess the vaccine supply on a continuing basis throughout the manufacturing period. CDC and state and local health authorities will inform providers and the general public if any indication exists of a substantial delay or an inadequate supply.

BOX. Initial target groups for novel influenza A (H1N1) vaccination programs and a subset of these target groups to receive vaccine if initial vaccine availability is not sufficient to meet demand*

Initial target groups

ACIP recommends that programs and providers provide vaccine to all persons in the following five initial target groups as soon as vaccine is available (order of target groups does not indicate priority):

- pregnant women,
- persons who live with or provide care for infants aged <6 months (e.g., parents, siblings, and daycare providers),
- 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.§

Subset of initial target groups

ACIP recommends that all persons in the following subset of the five initial target groups receive priority for vaccination if vaccine availability is not sufficient to meet demand (order of target groups does not indicate priority):

- pregnant women,
- persons who live with or provide care for infants aged <6 months (e.g., parents, siblings, and daycare providers),
- health-care and emergency medical services personnel who have direct contact with patients or infectious material,
- children aged 6 months–4 years, and
- children and adolescents aged 5–18 years who have medical conditions that put them at higher risk for influenza-related complications.§

* Priority should be given to persons in the subset of the five target groups only if initial vaccine availability is not sufficient to meet demand for all persons in the five target groups. As vaccine availability increases, vaccination programs should be expanded to include all members of the initial target groups. Vaccination of other adult populations is recommended as vaccine availability increases.

† Health-care personnel (HCP) include all paid and unpaid persons working in health-care settings who have the potential for exposure to patients with influenza, infectious materials, including body substances, contaminated medical supplies and equipment, or contaminated environmental surfaces. HCP might include (but are not limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the health-care facility, and persons (e.g., clerical, dietary, housekeeping, maintenance, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCP. The recommendations in this report apply to HCP in acute-care hospitals, nursing homes, skilled nursing facilities, physicians' offices, urgent care centers, and outpatient clinics, and to persons who provide home health care and emergency medical services. Emergency medical services personnel might include persons in an occupation (e.g., emergency medical technicians and fire fighters) who provide emergency medical care as part of their normal job duties.

§ Medical conditions that confer a higher risk for influenza-related complications include chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, cognitive, neurologic/neuromuscular, hematologic, or metabolic disorders (including diabetes mellitus) and immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus).

Current studies indicate the risk for infection among persons aged ≥65 years is less than the risk for persons in younger age groups. Expanding vaccination recommendations to include adults aged ≥65 years is recommended only after assessment of vaccine availability and demand at the local level. Once demand for vaccine among younger age groups is being met, vaccination should be expanded to all persons aged ≥65 years. This recommendation might need to be reassessed as new epidemiologic, immunologic, or clinical trial data warrant and in the context of global need for vaccine.

ACIP makes the following additional recommendations about use of influenza A (H1N1) 2009 monovalent vaccine:

- The number of doses of vaccine required for immunization against novel influenza A (H1N1) has not been established. Because vaccine availability is expected to increase over time, vaccine should not be held in reserve for patients who already have received 1 dose but might require a second dose.
- Simultaneous administration of inactivated vaccines against seasonal and novel influenza A (H1N1) viruses is permissible if different anatomic sites are used. However, simultaneous administration of live, attenuated vaccines against seasonal and novel influenza A (H1N1) virus is not recommended.
- All persons currently recommended for seasonal influenza vaccine, including those aged ≥65 years, should receive the seasonal vaccine as soon as it is available. Recommendations for use of the 2009–10 seasonal influenza vaccine have been published previously (*12*).

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☆U.S. Government Printing Office: 2009-523-019/41201 Region IV ISSN: 1057-5987

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CLINICIAN GUIDANCE KEY POINTS

Novel 2009 H1N1 influenza continues to be seen in Kentucky.

Novel 2009 H1N1 influenza virulence is comparable to seasonal influenza but older age groups (aged 60 years and older) are less likely to be infected with novel 2009 H1N1 influenza.

Definitive Testing – Most patients with influenza will **NOT** require definitive diagnostic virology testing. Kentucky Division of Laboratory Services is requesting specimens **ONLY** from individuals with acute febrile respiratory illness in the following groups (Please indicate on the laboratory specimen paperwork the group(s) that applies):

- **Pregnant women**
- **Hospitalized patients**
- **Institutionalized patients** (in institutions where previous cases have not been identified)

Treatment

- **The majority of persons with 2009 H1N1 influenza will NOT require treatment with antiviral medication.**
- Consider antiviral treatment if patient has severe illness or a risk factor for severe illness. - **Refer to KDPH ANTIVIRAL KEY POINTS (Following Page)**
- Consider bacterial pneumonia and bacterial co-infections in patients who suddenly worsen. In past pandemics, bacterial co-infections caused by *Streptococcus pneumoniae*, *Haemophilis influenzae, Staphylococcus aureus,* and group A *Streptococcus* have been contributors to morbidity and mortality.

Prevention

- People with influenza-like illness (ILI) should remain at home until at least 24 hours after they are free of fever (100° F [37.8°C]), or signs of a fever without the use of fever-reducing medications.
- Proper hand washing with soap and warm water
- Coughing in sleeve or elbow
- Avoiding contact with sick people
- Vaccination for both seasonal influenza and 2009 H1N1 influenza
- Chemoprophylaxis with neuraminidase inhibitors for high-risk close contacts of probable or confirmed human cases caused by novel 2009 H1N influenza
- Encouraging the use of pneumococcal vaccine in high risk groups to prevent some secondary bacterial infections.

Reporting

- **All hospitalized pregnant women with ILI** or confirmed influenza A infection should be reported to the Kentucky Department for Public Health at **1-888-9REPORT**
- **All pediatric deaths** related to influenza infection should be reported to the Kentucky Department for Public Health at **1-888-9REPORT**

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ANTIVIRAL KEY POINTS

General Information

- Full CDC Document (9/8/2009): http://www.cdc.gov/H1N1flu/recommendations.htm
- 2009 H1N1 influenza likely to be most common type for 2009 influenza season
- 2009 H1N1 influenza is *currently* susceptible to oseltamivir and zanamivir
- Treatment/prophylaxis dosing available at http://www.cdc.gov/H1N1flu/eua
- An inadequate supply of Tamiflu oral suspension exists but the suspension can be compounded by any pharmacist (see Treatment section of KDPH Letter to Clinicians for details)

Antiviral Treatment is NOT Indicated for Most People; However, Antiviral Treatment Is Indicated for These Groups:

- Hospitalized cases of suspected/confirmed 2009 H1N1 influenza
- High-risk (described below) cases with suspected/confirmed 2009 H1N1 influenza
- Suspected/confirmed cases with warning signs/symptoms of severe illness, e.g., dyspnea, tachypnea, and unexplained oxygen desaturation

Treat Early and Proactively When Indicated

- Ideally within 48 hours of onset of symptoms
- Rapid consultation and clinical evaluation for high-risk (described below) patients

High-Risk for Severe Illness

- Pregnant women
- Children less than 5 years old, especially less than 2 years old
- Persons aged 65 years or older (because they are more likely to have severe complications if infected)
- Persons with certain chronic or immunosuppressed conditions (asthma, cardiovascular, renal, hepatic, hematologic, neurologic, neuromuscular, or metabolic disorders)
- Children less than 19 years old on long-term aspirin therapy

Antiviral Chemoprophylaxis Can Be Considered for:

- Individuals at high-risk (described above) who have close contact with persons likely to have active 2009 H1N1 influenza infection
- Health care workers who have close contact with persons likely to have active 2009 H1N1 influenza infection
- Chemoprophylaxis generally is not recommended if more than 48 hours have elapsed since the last contact with an infectious person

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Dear Kentucky Clinician:

The ongoing pandemic caused by novel 2009 H1N1 influenza A virus continues to expand in Kentucky, in the United States, and internationally. The Centers for Disease Control and Prevention (CDC) and the Kentucky Department for Public Health (KDPH) expect that more cases, more hospitalizations, and more deaths from this pandemic will occur over the coming weeks to months.

SURVEILLANCE

Kentucky experienced a steady, but low rate of novel 2009 H1N1 influenza activity over the Summer and into the Fall. In recent weeks, almost all laboratory specimens that have tested positive for influenza A virus at KDPH's Division of Laboratory Services (DLS) have been the novel 2009 H1N1 influenza virus rather than seasonal influenza virus. Following CDC's lead, KDPH is no longer counting individual cases of novel 2009 H1N1 influenza infection, but rather using usual statewide influenza surveillance methods to report aggregate levels of activity. At this time, surveillance in the state indicates widespread flu activity. Most of this activity is due to 2009 H1N1 influenza, because it is the predominant circulating strain of flu. As of September 12, 2009, 99% of circulating influenza viruses across the U.S. were 2009 H1N1 influenza viruses susceptible to both oseltamivir (Tamiflu) and zanamivir (Relenza).

REPORTING

KDPH requests that **all hospitalized pregnant women with influenza-like illness OR confirmed influenza A infection** and **all pediatric seasonal and 2009 H1N1 influenza-associated deaths** be reported to the Kentucky Department for Public Health at **1-888-9REPORT.**

TESTING

Since more influenza cases caused by novel 2009 H1N1 influenza virus are anticipated to occur in Kentucky in the next few weeks to months, clinicians should use appropriate medical judgment, surveillance data and recommended public health guidelines to make determinations about laboratory testing or the use of antivirals. Most patients who present with influenza-like illness during the next few months will likely have novel 2009 H1N1 influenza infection. The sensitivity of rapid tests ranges from 10-70%, therefore, a negative test may not rule out influenza. Fortunately, many patients who have been infected with 2009 H1N1 influenza virus infection, but who are not in a high-risk group, have had a self-limited respiratory illness similar to typical seasonal influenza (http://www.cdc.gov/H1N1flu/recommendations.htm).

Because of novel 2009 H1N1 influenza's comparable severity to seasonal flu, most patients with influenza will NOT require definitive diagnostic virology testing in order to receive appropriate treatment and guidance on preventing further transmission. However, KDPH requests that specimens from patients who meet the following criteria be sent to the DLS in Frankfort.

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Criteria for Submission of Laboratory Specimens to the Division of Laboratory Services:

Currently, KDPH is asking the health care community to submit specimens for novel 2009 H1N1 influenza virus testing *only* from patients with *acute febrile respiratory illness* who are *(Please indicate on the laboratory specimen paperwork the group(s) that applies)*:

(1) *pregnant* ***OR***

(2) *have a clinical condition that has required hospitalization* ***OR***

(3) *are living in an institutional setting where previous cases have not been identified*.

KDPH does not request specimens from patients who are contacts of confirmed cases, unless they meet the above criteria. KDPH also does not request specimens from patients who have been observed for prolonged times in Emergency Rooms or other observation areas but were discharged prior to 24 hours of care. Furthermore, specimens from patients who test positive for rapid influenza A are not requested, unless the patient meets the criteria stated in the box above. If patients do not meet the criteria for testing at DLS, but the clinician feels a need to test, specimens can be sent by health care providers to private (non-public health) reference laboratories that are also performing novel 2009 H1N1 influenza testing.

When definitive novel 2009 H1N1 influenza testing is indicated at DLS based on the above criteria, the following should be collected as soon as possible after illness onset: nasopharyngeal swab, nasal aspirate or a combined nasopharyngeal swab with oropharyngeal swab. If these specimens cannot be collected, a nasal swab or oropharyngeal swab is acceptable. Per CDC guidance, nasal washes are no longer recommended for specimen collection. Ideally, swab specimens should be collected using swabs with a synthetic tip (e.g. polyester or Dacron®) and an aluminum or plastic shaft. Swabs with cotton tips and wooden shafts **are not recommended**. Specimens collected with swabs made of calcium alginate are not acceptable. Specimens should be placed into 1 to 3 mL sterile viral transport medium (M4RT) and immediately placed on ice or cold packs or at 4°Celsius (refrigerator) for transport to the laboratory. Label specimen container, package and ship to DLS, as directed at: http://www.chfs.ky.gov/dph/info/lab/. Before sending the specimen to DLS, please call DLS at 502-564-4446 for tracking and guidance.

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TREATMENT

The majority of patients with influenza will probably not need antivirals prescribed for their illness. Treatment is recommended for any suspected/confirmed case of 2009 H1N1 influenza which requires hospitalization. Treatment is also recommended for all high-risk (described below) suspected/confirmed cases. Treatment is further recommended for suspected/confirmed cases with warning signs/symptoms of severe illness, such as dyspnea, tachypnea, and unexplained oxygen desaturation.

The following groups of persons are at high-risk for severe illness: 1) children younger than 5 years old, especially those younger than 2 years old; 2) adults aged 65 years or older (because they are more likely to have severe complications if infected); 3) pregnant women; 4) persons with chronic conditions, such as pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, hematological (including sickle cell disease), neurologic, neuromuscular, or metabolic disorders (including diabetes mellitus); 5) immunosuppressed individuals, including medication-induced and HIV-positive; 6) persons younger than 19 years old who are receiving long-term aspirin therapy (due to an increased risk for Reye syndrome). Treatment is not recommended for those without risk factors for severe complications who present with uncomplicated febrile illnesses.

Ideally, treatment should begin within 48 hours of illness onset. Antiviral doses recommended for treatment of respiratory infections caused by H1N1 influenza in adults or children 1 year of age or older are the same as those recommended for seasonal influenza. Treatment dosing is available at: http://www.cdc.gov/H1N1flu/eua. Oseltamivir use for children younger than 1 year old was recently authorized by the U.S. Food and Drug Administration (FDA) under an Emergency Use Authorization (EUA) and dosing for these children is age-based although some experts prefer weight-based dosing, particularly for premature or underweight infants. Please see the CDC recommendations at: http://www.cdc.gov/h1n1flu/eua/tamiflu.htm.

For current information for clinical considerations of **pregnant women** please see CDC recommendations at: http://www.cdc.gov/h1n1flu/clinician_pregnant.htm

2009 H1N1 influenza viruses are susceptible to the neuraminidase inhibitor antiviral medications, oseltamivir and zanamivir, but are resistant to the adamantane antiviral medications, amantadine and rimantadine. This susceptibility pattern is the same as that observed among seasonal influenza A (H3N2) and B viruses in recent years. Oseltamivir resistance appears to be rare at this time. However, oseltamivir-resistant 2009 H1N1 influenza viruses have been identified, typically among persons who develop illness while receiving oseltamivir for chemoprophylaxis or immunocompromised patients with influenza who are being treated. **These findings underscore the importance of careful and limited use of antiviral medications for chemoprophylaxis and the need for persons taking antiviral medications to continue to follow recommendations for hand and respiratory hygiene to prevent the spread of antiviral resistant viruses.** Additional information on oseltamivir resistance among 2009 H1N1 influenza viruses is available at: http://www.cdc.gov/h1n1flu/HAN/070909.htm.

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Chemoprophylaxis dosing is available at http://www.cdc.gov/H1N1flu/eua. Chemoprophylaxis should be considered in high-risk individuals (described above) who have close contact with persons likely to have active 2009 H1N1 influenza such as those in group settings such as nursing homes or correctional facilities. Health care workers who have close contact with such persons should also consider chemoprophylaxis. Chemoprophylaxis is not recommended if more than 48 hours have passed since last contact with an infectious person. Chemoprophylaxis is not recommended for healthy children or adults in group settings, such as schools, camps, and workplaces.

Currently the national commercial supply chain for Tamiflu oral suspension may be inadequate. KDPH has released guidance for pharmacists to compound suspensions following guidelines from the FDA. This information can be found at: http://healthalerts.ky.gov/Pages/HealthProfessionalsInfo.aspx under "Updated Clinician's Guidance for Pediatric Prescription of oseltamavir (Tamiflu) for H1N1 Treatment" (September 28, 2009)

Through a network of participating pharmacies, KDPH is implementing a program in collaboration with the Kentucky Pharmacists Association **for those patients who cannot afford the cost of antiviral medicines** that have been prescribed. State stock antiviral medications are available in limited supply to serve the uninsured and underinsured who otherwise could not afford the cost of the antiviral medication they have been prescribed. If a patient is given a prescription for antiviral medication but is unable to pay for the cost of getting the prescription filled, then state stockpiles of antivirals can be used to fill the prescription either without charge or for a minimal $5 fee, but only at participating pharmacies. In an effort to control and monitor for proper use and dispensing of the state owned antiviral cache, **prescribers should identify on the prescription "*KPhA Rx*" which will alert the participating pre-identified pharmacies to utilize the state cache to dispense antivirals to those who cannot otherwise pay for them**. More information about this program and its participating pharmacies will be sent in the near future.

During previous influenza pandemics**, bacterial co-infections caused by *Streptococcus pneumoniae, Haemophilis influenzae, Staphylococcus aureus,* and group A *Streptococcus* have been contributors to morbidity and mortality.** A recent MMWR article **(October 2, 2009 / 58(38):1071-1074)** reported that these same pathogens were identified in lung tissue from 22 of 77 cases of fatal H1N1 influenza A infections. Bacterial pneumonia and bacterial coinfections should be considered in patients with ILI or confirmed influenza illnesses who suddenly worsen.

SCHOOL AND WORKPLACE EXCLUSION

CDC has recently issued guidance related to school and work exclusion policies for persons with influenza-like illness. **"CDC recommends that people with influenza-like illness remain at**

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home until at least 24 hours after they are free of fever (100° F [37.8°C]), or signs of a fever without the use of fever-reducing medications." This is a change from the previous recommendation that ill persons stay home for 7 days after illness onset or until 24 hours after the resolution of symptoms, whichever was longer. The new recommendation applies to camps, schools, businesses, mass gatherings, and other community settings where the majority of people are not at increased risk for influenza complications. This guidance does not apply to health care settings "where the exclusion period should be continued for 7 days from symptom onset or until the resolution of symptoms, whichever is longer,"
http://www.cdc.gov/H1N1flu/guidance/exclusion.htm

PREVENTION

Transmission of 2009 H1N1 influenza and seasonal influenza appear to be by similar mechanisms. Spread of both seasonal influenza and 2009 H1N1 influenza can be prevented through proper handwashing, coughing in one's elbow or sleeve, avoiding contact with sick persons, and staying home from school or work if illness occurs.

Vaccination is the best way to prevent influenza. The initial shipments of the vaccine against 2009 H1N1 influenza started becoming available in October from the federal government. This vaccine is separate from seasonal influenza vaccine. Based on the epidemiology of the illnesses, target groups for the two vaccines are distinct, though there is some overlap in the targeted groups: http://www.cdc.gov/flu/professionals/vaccination/ and http://www.cdc.gov/H1N1flu/vaccination/ . If your clinic or facility is interested in receiving and administering novel 2009 H1N1 influenza vaccine please contact your local health department.

There are four different brands for 2009 H1N1 vaccines. Indications and contraindications vary by brand and formulation. Details for each specific type are available at the following FDA site: http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm181950.htm. Summarized information is available in the protocol section of the following KDPH site: http://healthalerts.ky.gov/Pages/H1N1InfluenzaToolkitforClinicians(Fall2009).aspx. Although additional considerations vary by specific brand and formulation, the following information is true for all types. Children less than 9 years old require two doses of vaccine given one month apart. People 10 years old and older require only one dose of vaccine. Contraindications include life-threatening reactions to previous influenza vaccine as well as hypersensitivity to eggs or vaccine components. Only IM vaccines from multi-dose vials contain the preservative thimerosal. Details about thimerosal are available at these CDC sites.
http://www.cdc.gov/FLU/ABOUT/QA/thimerosal.htm
http://www.cdc.gov/h1n1flu/vaccination/thimerosal_qa.htm The 2009 H1N1 influenza vaccine is being made by the same processes used for seasonal influenza vaccine and is expected to have a similar safety profile: http://www.cdc.gov/h1n1flu/vaccination/vaccine_safety_qa.htm Any adverse events related to vaccine administration should be reported through the Vaccine Adverse Events Reporting System (VAERS), as is customary for events related to any vaccine. A VAERS form may be downloaded from the VAERS website at http://vaers.hhs.gov/esub/index. Alternatively, you may request a VAERS form by sending an email to: info@vaers.org, by calling toll-free 800-822-7967, or by sending a faxed request to 877-721-0366.

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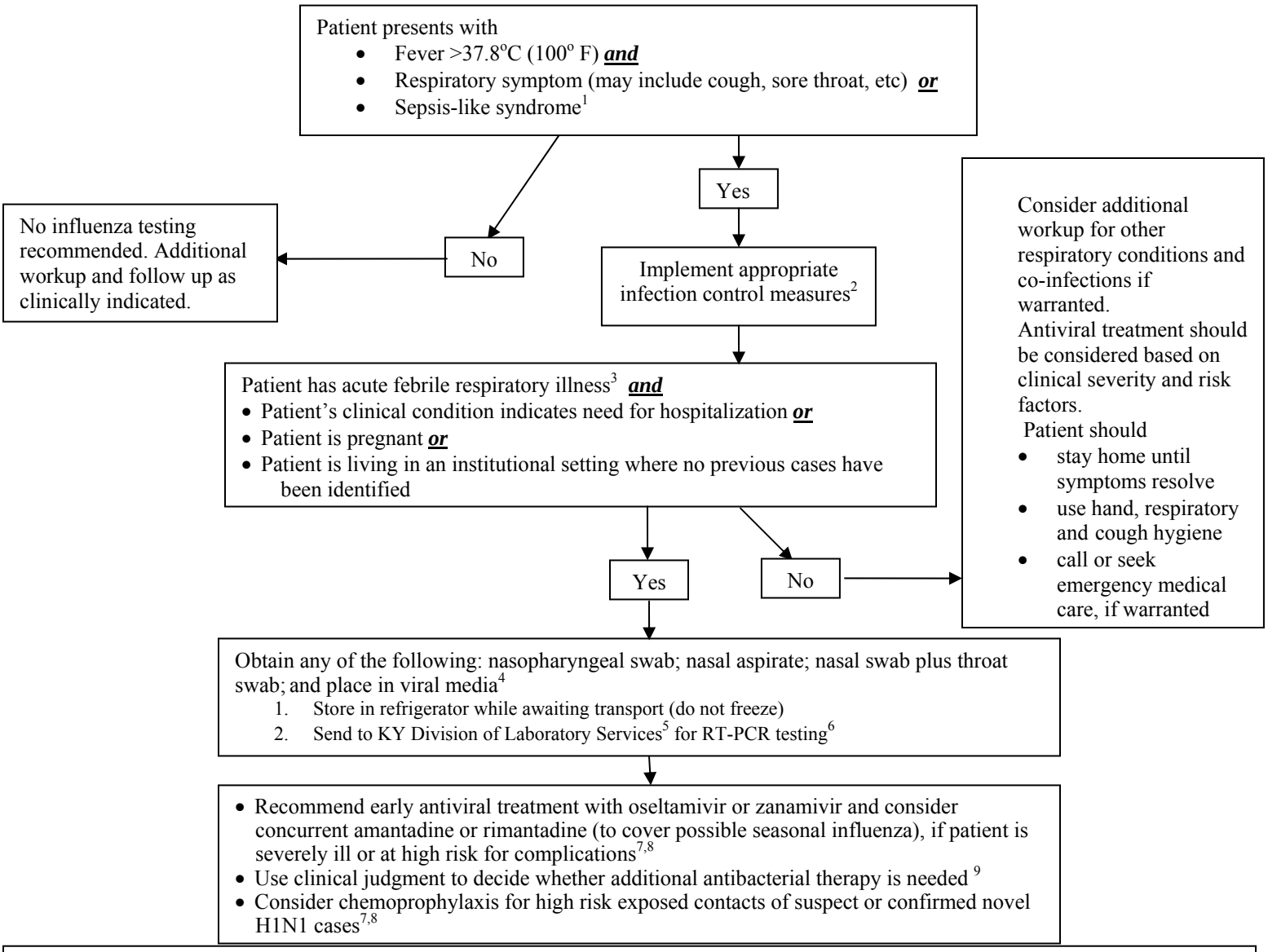
Recent findings published in MMWR (http://www.cdc.gov/mmwr October 2, 2009 / 58(38);1071-1074) confirm that **bacterial lung infections are occurring among patients with fatal cases of novel 2009 H1N1 influenza** and underscore both the importance of pneumococcal vaccination for persons at increased risk for pneumococcal pneumonia and the need for early recognition and treatment of bacterial pneumonia in persons with influenza. Persons at greatest risk for invasive pneumococcal disease include young children, older adults, and persons of any age with certain conditions, including chronic lung or cardiovascular disease and immunosuppressive conditions. All children aged less than 5 years should receive pneumococcal conjugate vaccine (PCV7) according to current Advisory Committee on Immunization Practices (ACIP) recommendations. In addition, pneumococcal polysaccharide vaccine (PPSV23) is recommended for all persons aged 2 through 64 years with certain health conditions and all persons aged 65 years and older.

Thank you for your willingness to work with us to prevent and appropriately treat influenza. Please see our newly available Clinician Toolkit at: http://healthalerts.ky.gov/Pages/H1N1InfluenzaToolkitforClinicians(Fall2009).aspx for extensive literature on all aspects of H1N1 prevention and treatment. More information, including guidance for health care workers, PPE recommendations, and care of patients in the home, can be found at KDPH's Health Alerts website (http://healthalerts.ky.gov) and the federal government flu website (www.flu.gov).

CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR PUBLIC HEALTH

Updated interim algorithm for clinicians to assist in decisions on testing and treatment for novel H1N1 (swine flu) virus in Kentucky
August 26, 2009



1. As with seasonal influenza, infants, adults ≥65 years-old, and persons with compromised immune systems may have atypical presentations.
2. Information on infection control can be found at: http://www.cdc.gov/h1n1flu/guidelines_infection_control.htm
3. If you encounter a patient that may have extenuating circumstances that warrant testing, please contact Emily Adkins, RN at 502-564-5353 during regular business hours. If the situation is urgent and outside of business hours, please call our after hours contact line at 888-9REPORT.
4. See KY Division of Laboratory Services website: www.chfs.ky.gov/dph/info/lab
5. KY Division of Laboratory Services: ATTN: Virology, 100 Sower Blvd. Frankfort, KY 40601
6. Real-time polymerase chain reaction (RT-PCR) is the preferred laboratory test for identifying novel H1N1 (swine flu) virus. Rapid antigen tests and immunofluorescence tests have unknown sensitivity and specificity to detect novel H1N1 virus. For more information, please see http://www.cdc.gov/h1n1flu/specimencollection.htm.
7. Persons at high risk of complications: Children less than 5 years old; persons aged 50 years or older; children and adolescents (aged 6 months–18 years) who are receiving long-term aspirin therapy and who might be at risk for experiencing Reye syndrome after influenza virus infection; pregnant women; adults and children who have chronic pulmonary, cardiovascular, hepatic, hematological, neurologic, neuromuscular, or metabolic disorders; adults and children who have immunosuppression (including immunosuppression caused by medications or by HIV); and residents of nursing homes and other chronic-care facilities.
8. Information on use of antiviral agents can be found at: http://www.cdc.gov/h1n1flu/recommendations.htm
9. Interim guidance for clinicians is available at: http://www.cdc.gov/h1n1flu/clinicians/

Please note: this algorithm does *not* apply to providers participating in the US Outpatient Influenza-like Illness Surveillance Network (ILINet). For guidance related to ILI Net see: http://www.cdc.gov/h1n1flu/screening.htm

Updated on 8/26/2009

CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR PUBLIC HEALTH

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Janie Miller
Secretary

August 28, 2009

Dear Kentucky Clinician:

The ongoing outbreak of novel influenza A (H1N1) continues to expand during the summer months, causing illness, hospitalizations, and deaths in the US. The Kentucky Department for Public Health and the Centers for Disease Control and Prevention (CDC) are concerned that the new H1N1 flu virus could result in a particularly severe flu season this year. A novel H1N1 vaccine is currently in production and may be ready for administration to the public in the fall. The novel H1N1 vaccine is not intended to replace the seasonal flu vaccine – it is intended to be used along-side seasonal flu vaccine. CDC is recommending providers begin vaccinating against seasonal influenza as soon as vaccines become available. The novel H1N1 vaccine will be government-purchased vaccine so it will be distributed through a different mechanism than usual and providers will not be charged for receipt of the vaccine.

Your practice most likely sees patients that fall into one or more of the priority groups recommended to receive the novel H1N1 vaccine (see below). The Kentucky Department for Public Health (KDPH) is requesting the assistance of Kentucky clinicians in providing the vaccination against novel H1N1 when vaccine becomes available. We encourage all clinicians and practices to consider participating, especially those who carry a high patient load of the priority groups identified below. To give us an indication of your practice's willingness to participate in this important vaccination campaign, please log onto: https://khelps.chfs.ky.gov and fill in the requested information. Only one registration per facility is needed so please coordinate with other providers in your practice as needed. On the website, we ask for an estimate of the number of doses your practice might administer – keep in mind that this is only a "best guess" and is not meant to be binding.

In the interest of transparency we want to be clear that distribution of vaccine will be based on a number of factors, not all of which are available at this time, so registration is not a guarantee of receipt of vaccine, just your willingness to provide novel H1N1 vaccination. All providers who register will be updated regarding novel H1N1 vaccine distribution and administration as more information becomes available.

CDC's Advisory Committee on Immunization Practices (ACIP) met on July 29, to consider who should receive novel H1N1 influenza vaccine. The ACIP considered several factors, including current disease patterns, populations most at-risk for severe illness based on current trends in illness, hospitalizations and deaths, how much vaccine is expected to be available, and the timing of vaccine availability.

The groups recommended to first receive the novel H1N1 influenza vaccine include:

1) **Pregnant women** - higher risk of H1N1 complications. Vaccine can also potentially provide immunity and protection to infants less than six months of age who cannot be vaccinated;
2) **Household contacts and caregivers for children younger than 6 months of age** - younger infants are at higher risk of complications from the H1N1 virus but cannot be vaccinated. Vaccination of those in close contact with infants <6 months should help protect them by "cocooning" them from the virus;
3) **Healthcare and emergency medical services personnel -** infections among healthcare workers have been reported and they can be a potential source of infection for vulnerable patients. Also, increased absenteeism in this population could reduce healthcare system capacity;
4) **All people from 6 months through 24 years of age**
   - **Children from 6 months through 18 years of age -** there have been many cases of novel H1N1 influenza in children, and they are in close contact with each other in school and day care settings, which increases the likelihood of disease spread;
   - **Young adults 19 through 24 years of age** - there have been many cases of novel H1N1 influenza in these healthy young adults and they often live, work, and study in close proximity, and they are a frequently mobile population;
5) **Persons aged 25 through 64 years who have health conditions associated with higher risk of medical complications from influenza.**

CDC does not expect that there will be a shortage of novel H1N1 vaccine, but vaccine availability and demand can be unpredictable. The ACIP made recommendations regarding which people within the at-risk groups listed above should be prioritized if the vaccine is initially available in limited quantities. We will provide those who are registered with regular updates and communications regarding this as the situation evolves.

Once again, if your practice is considering administering novel H1N1 vaccine, please register the practice at https://khelps.chfs.ky.gov. The novel H1N1 vaccine will be supplied free of charge to your practice by CDC through KDPH. The process is expected to be very similar to the method used by the Vaccines for Children (VFC) program. As with the VFC program, clinicians will be expected to sign a provider agreement with KDPH. Providers will be allowed to charge an administration fee, if you desire, and this will be detailed in our provider agreement. There is a worksheet provided below to help assess the number of doses you will need based on the distribution of the novel H1N1 priority populations in your practice setting. The vaccine is projected to be administered to all recipients as a two-dose series; please be aware of this as you determine the number of doses based on patients that would fall into each of the priority groups as well as the number of staff you have to vaccinate.

Thank you for your attention to this issue and your consideration of our request.

Sincerely,

William D. Hacker, MD, FAAP, CPE
Commissioner

Novel H1N1 Influenza Vaccine Worksheet

RISK GROUPS	**NUMBER OF DOSES NEEDED FOR EACH RISK GROUP** (@ 2 doses/person)
Pregnant women:	
Household contacts and caregivers for children younger than 6 months of age:	
Healthcare and emergency medical services personnel:	
Persons aged 6 months through 24 years	
Persons aged 25 through 64 years who have health conditions associated with higher risk of medical complications from influenza:	
TOTAL NUMBER OF DOSES NEEDED:	

Protocol for the Administration of Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal

***Please compare the Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal package insert with the LAIV package insert and LAIV protocol. Some of the recommendations in this protocol are not included in the package insert for Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal, but they can be found in the LAIV package insert and LAIV protocol and are considered prudent guidance by the Kentucky Immunization Program.**

Indications and Usage: Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal is indicated for the active immunization of individuals against influenza disease caused by pandemic (H1N1) 2009 virus. It is a live, nasally administered vaccine approved for use ONLY among healthy **nonpregnant** persons aged 2 through 49 years.

Vaccination efforts with Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal should focus **initially** on persons likely to come in contact with influenza viruses as part of their occupation and could transmit influenza viruses to others in medical care settings, or are close contacts of infants aged less than 6 months (who are too young to be vaccinated).

Persons for whom vaccination with Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal is recommended

Initially:

- Healthy children, adolescents and adults (aged 2 through 24 years) except for pregnant adolescents and adults;
- Healthy healthcare and emergency medical services personnel (HCP and EMS personnel), aged 49 years or less, except for pregnant HCP and EMS personnel);
- Healthy household contacts and caregivers (aged 2 through 49 years), except for pregnant women, of infants aged less than 6 months (e.g., parents, siblings, and daycare providers).

Per ACIP, health-care personnel (HCP) recommended for priority vaccination include those in acute-care hospitals, nursing homes, skilled nursing facilities, physicians' offices, urgent care centers, and outpatient clinics. The recommendations also apply to persons who provide home health care and emergency medical services.

Simultaneous administration of seasonal and H1N1 influenza vaccines

- You can administer both the inactivated seasonal influenza vaccine and the inactivated Influenza A (H1N1) 2009 Monovalent Vaccine at the same visit (using separate syringes and sites) or at any time before or after each other.
- You can administer the inactivated seasonal influenza vaccine and Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal together or at any time before or after each other.
- You can administer the seasonal live attenuated influenza virus vaccine and inactivated Influenza A (H1N1) 2009 Monovalent Vaccine together or at any time before or after each other.
- Administering both the seasonal live attenuated influenza virus vaccine and Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal at the same visit **IS NOT RECOMMENDED** because of concerns about competition between the two vaccine viruses. If you have only seasonal live attenuated influenza virus vaccine and Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal available, you should separate the doses of the two live attenuated influenza virus vaccines by at least 4 weeks.

Dosage and Route

Age group	Dosage Schedule
Children (aged 2 through 9 years)	2 doses (0.2 mL each approximately 1 month apart)
Children, adolescents and adults (aged 10 through 49 years)	1 dose (0.2 mL)

Each 0.2 mL dose is administered as 0.1 mL per nostril. Note that the age groups for the two dose schedule is for children aged 2 through 9 years, whereas the two dose series for seasonal Live Attenuated Influenza Vaccine is for children aged 2 through 8 years.

To administer the vaccine (See the product package insert for complete step-by-step instructions):

- Place the recipient in an upright position
- Remove the rubber tip protector from the sprayer. Do not remove the dose-divider clip at the other end of the sprayer.
- Place the tip just inside the first nostril
- With a single motion, depress plunger **as rapidly as possible** until the dose-divider clip prevents you from going further
- Pinch and remove the dose-divider clip from the plunger
- Place the tip just inside the other nostril and with a single motion, depress plunger **as rapidly as possible** to deliver remaining vaccine

Anatomical Site: Intranasal [**Under no circumstances should Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal be administered by the intramuscular, intradermal, or intravenous route.]**

Precautions

- If Guillain-Barré Syndrome has occurred with any prior influenza vaccination, the decision to give Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal should be based on careful consideration of the potential benefits and risks.
- Moderate or severe illness with or without fever, postpone administration of the vaccine until recovery from the acute phase of moderate or severe illness.
- Because antivirals reduce replication of influenza viruses, Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal should not be administered until 48 hours after cessation of influenza antiviral therapy and influenza antiviral medications should not be administered for two weeks after receipt of Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal. Persons receiving antivirals within the period 2 days before to 14 days after vaccination with Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal should be revaccinated at a later date with any approved Influenza A (H1N1) 2009 vaccine formulation.
- Defer administration of Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal if nasal congestion is present.

Contraindications

- Persons with a history of hypersensitivity, including anaphylaxis, to eggs, egg proteins, gentamicin, gelatin, arginine or any previous influenza vaccination;
- Persons aged less than 2 years or those aged 50 years and older;
- Adults and children who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, neurological/neuromuscular, hematological, or metabolic disorders (including diabetes mellitus);
- Adults and children who have immunosuppression (including immunosuppression caused by medications or by HIV);
- Children aged 2 through 4 years whose parents or caregivers report that a health-care provider has told them during the preceding 12 months that their child had wheezing or asthma, or whose medical record indicates a wheezing episode has occurred during the preceding 12 months;
- Children or adolescents aged 2 years through 18 years receiving aspirin or other salicylates (because of the association of Reye's syndrome with wild-type influenza virus infection);
- Pregnant women;
- Close contacts of immunosuppressed persons who require a protected environment.

Screening for asthma or wheezing illness (or history of wheezing illness) when considering use of Live Influenza A (H1N1) 2009 Monovalent Vaccine for children aged 2 through 4 years

- Clinicians and vaccination programs should screen for asthma or wheezing illness (or history of wheezing illness) when considering use of Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal for children aged 2 through 4 years, and should avoid use of this vaccine in children with asthma or a recent wheezing episode within the previous 12 months.
- Health-care providers should consult the medical record, when available, to identify children aged 2 through 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 Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal, parents or caregivers of children aged 2 through 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 during the preceding 12 months **should not** receive Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal.

Warnings

The following children, adolescents, and adults **SHOULD NOT** be vaccinated with Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal but should receive Inactivated Influenza A (H1N1) 2009 Monovalent Vaccine if 6 months of age or older:

- Children aged less than 2 years;
- Adults aged 50 years and older;
- Persons with asthma, reactive airways disease or other chronic disorders of the pulmonary or cardiovascular systems;
- Persons with other underlying medical conditions, such as the metabolic diseases, diabetes, renal dysfunction, and hemoglobinopathies;
- Pregnant women;
- Household or other close contacts of a person with severe immunosuppression requiring care in a protective environment.

Adverse Events—See the product's package insert.

Storage and Handling

- Store between 35°-46°F (2°-8°C) DO NOT FREEZE.
- The product must be used before the expiration date on the sprayer label.

Other Important Notes –

Shedding Vaccine virus

- Nasopharyngeal secretions or swabs collected from vaccinees may test positive for influenza virus for up to three weeks post immunization.

Administering Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal

- Severely immunosuppressed persons should not receive Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal.

Healthcare personnel or hospital visitors

- Who have received Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal should refrain from contact with severely immunosuppressed patients requiring a protective environment for 7 days after receipt of vaccine. Inactivated Influenza A (H1N1) 2009 Monovalent Vaccine is recommended for vaccinating household members, HCP, and others who have close contact with severely immunosuppressed persons (e.g. patients with hematopoietic stem cell transplants) requiring care in a protective environment.
- Hospital visitors who have received Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal should avoid contact with severely immunosuppressed persons in protected environments for 7 days after vaccination but should not be restricted from visiting less severely immunosuppressed patients.

_____ _____

M.D. Signature **Date**

Protocol for the Administration of Inactivated Influenza A (H1N1) 2009 Monovalent Vaccine

Indications and Usage: Influenza A (H1N1) 2009 Monovalent Vaccine is an inactivated influenza virus vaccine indicated for active immunization against influenza disease caused by pandemic (H1N1) 2009 virus.

Vaccination efforts should focus initially on persons in five target groups (see below) whose members are at higher risk for influenza or influenza-related complications, are likely to come in contact with influenza viruses as part of their occupation and could transmit influenza viruses to others in medical care settings, or are close contacts of infants aged less than 6 months (who are too young to be vaccinated).

Initial target groups for inactivated Influenza A (H1N1) 2009 Monovalent Vaccine and a subset of these target groups to receive vaccine if initial vaccine availability is not sufficient to meet demand:

Initial target groups

ACIP recommends that programs and providers provide vaccine to all persons in the following five initial target groups as soon as vaccine is available (order of target groups does not indicate priority):

- pregnant women,
- persons who live with or provide care for infants aged less than 6 months (e.g., parents, siblings, and daycare providers),
- health-care and emergency medical services personnel,
- children and young adults aged 6 months through 24 years, and
- persons aged 25 through 64 years who have medical conditions that put them at higher risk for influenza-related complications.

Subset of initial target groups during limited vaccine availability

ACIP recommends that all persons in the following subset of the five initial target groups receive priority for vaccination if vaccine availability is not sufficient to meet demand (order of target groups does not indicate priority):

- pregnant women,
- persons who live with or provide care for infants aged less than 6 months (e.g., parents, siblings, and daycare providers),
- health-care and emergency medical services personnel who have direct contact with patients or infectious material,
- children aged 6 months through 4 years, and
- children and adolescents aged 5 years through 18 years who have medical conditions that put them at higher risk for influenza-related complications.

Per ACIP, health-care personnel (HCP) recommended for priority vaccination include those in acute-care hospitals, nursing homes, skilled nursing facilities, physicians' offices, urgent care centers, and outpatient clinics. The recommendations also apply to persons who provide home health care and emergency medical services.

Chronic medical conditions that may lead to a higher risk for influenza-related complications include chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, cognitive, neurologic/neuromuscular, hematologic, or metabolic disorders (including diabetes mellitus) or immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus).

Vaccination of other adult populations is recommended as vaccine availability increases.

Dosage and Route (See package insert for brands of Influenza A (H1N1) 2009 Vaccine being used

Age Group	Doses	No. of Doses
6 through 35 months	0.25 mL	2 doses one month apart
36 months through 9 years[1]	0.5 mL	2 doses one month apart
10 through 17 years	0.5 mL	1
18 years of age and older	0.5 mL	1

[1]Note only one vaccine brand is indicated for children 6 months to 4 years of age. Pay close attention to the brand of Influenza A (H1N1) 2009 Monovalent Vaccine being used.

Simultaneous administration of seasonal and H1N1 influenza vaccines

- You can administer both the inactivated seasonal influenza vaccine and the inactivated Influenza A (H1N1) 2009 Monovalent Vaccine at the same visit (using separate syringes and sites) or at any time before or after each other.
- You can administer the inactivated seasonal influenza vaccine and Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal together or at any time before or after each other.
- You can administer the seasonal live attenuated influenza virus vaccine and inactivated Influenza A (H1N1) 2009 Monovalent Vaccine together or at any time before or after each other.
- Administering both the seasonal live attenuated influenza virus vaccine and Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal at the same visit **IS NOT RECOMMENDED** because of concerns about competition between the two vaccine viruses. If you have only seasonal live attenuated influenza virus vaccine and Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal available, you should separate the doses of the two live attenuated influenza virus vaccines by at least 4 weeks

Anatomical Site for Administration of Inactivated Influenza A (H1N1) 2009 Monovalent Vaccine

- Intramuscular injection, dosage specific for age group. Adults and older children should be vaccinated in the deltoid muscle. Infants and young children should be vaccinated in the anterolateral aspect of the thigh. See the Pink Book, Epidemiology and Prevention of Vaccine-Preventable Diseases, for guidance on selecting proper needle lengths to administer intramuscular injections to different age groups. As with other intramuscular injections, use with caution in patients on anticoagulant therapy.

Precautions

- Guillain-Barré syndrome (GBS) within 6 weeks of receiving a previous dose of influenza vaccine.
- Immunocompromised persons may have a reduced immune response to inactivated Influenza A (H1N1) 2009 Monovalent Vaccine.

Contraindications

- Anaphylactic reaction to a previous dose of influenza vaccine; eggs or any other component of the vaccine (see package insert for specific components)
- Hypersensitivity to eggs or chicken protein, neomycin, or polymyxin

Refer persons with a history of anaphylaxis to a vaccine component, but who are at risk for complications from influenza, to their healthcare provider for evaluation, desensitization and possible administration of inactivated influenza A (H1N1) 2009 Monovalent Vaccine.

Adverse events—See the product's package insert.

Storage and Handling: Store between 35°-46°F (2°-8°C) **DO NOT FREEZE**. Store in the original package to protect from light. Discard if the vaccine has been frozen. See the product's package insert.

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M.D. Signature **Date**

EMERGENCIES

General Information:
LHDs must be able to respond to a range of medical emergencies, potentially violent or abusive situations, and facility or natural/weather related emergencies. Staff must be familiar with emergency supplies and equipment and trained in their use, as appropriate.

Procedures for non-medical emergencies such as fire, tornadoes/severe weather conditions, earthquakes, and bomb threats shall be addressed in the LHD's Emergency Evacuation and Fire Prevention Control Procedures Plan. Training is to occur on at least an annual basis. For further information, refer to the Administrative Reference, Vol. I, Section VIII-LHD Operations for LHDs. (Also see the Disaster Recovery and Response Plan Manual).

MEDICAL EMERGENCIES

LHDs should be prepared for medical emergencies, particularly, life-threatening drug reactions. Established procedures, adequate and properly maintained equipment, and appropriately trained staff are essential.

- Protocols for emergency care for anaphylactic reactions, and management of vasovagal reactions and syncope should be signed by a local physician and a copy kept with the emergency supplies.
- If the LHD stocks an Automated External Defibrillator (AED) device, they must develop and maintain local policies on its use and maintenance.
- LHD prepared for more extensive emergency measures should have a locally developed protocol in place to guide staff.
- Emergency equipment, supplies, and medications should be maintained on a crash cart or emergency tray.
- An inventory list is to be kept with the crash cart or emergency tray and monitored monthly according to an established schedule to ensure that they are not depleted or expired. Emergency supplies should be sealed when not in use.
- All physicians, clinicians and nurses should be certified in CPR
- All staff should be offered the opportunity to participate in CPR training
- At a minimum, all staff must know their role in an emergency situation.
- All staff should have access to the Poison Control phone number, 1-800-222-1222, and it should be posted in a prominent place.

EMERGENCY EQUIPMENT, SUPPLIES, AND MEDICATIONS

Inventory List*

(When Equipment and Supplies are replaced, LHDs should order Latex-free.)

- AMBU bag – at least 1 Adult and 1 Pediatric unit (Latex-free), checked for physical integrity at least monthly and replace per manufacturer's recommendations.
- One-way masks – small, medium, large; latex-free
- Sphygmomanometer, age appropriate, ex. pediatric, adult, extra-large – serviced according with manufacturer's recommendations
- Stethoscope
- Flashlight and extra batteries
- Oxygen tank with mask (serviced yearly and checked monthly)
- Syringes and needles of various sizes, including filtered needles for use with ampoules (for the removals of minute particles of glass, filtered needles are not to be used for administration.)
- Alcohol swabs or sponges
- Gloves, latex-free
- Aqueous epinephrine (1:1000; 1mL ampoules, at least 4 but more for medically isolated clinics)
- Diphenhydramine hydrochloride (Benadryl) Liquid; Diphenhydramine hydrochloride (Benadryl) 50 mg/mL vials (a minimum of 4)
- Atropine sulfate ampoules 0.4 mg/mL (optional)
- Aromatic ammonia (optional)
- Poison Control phone number 1-800-222-1222
  http://www.aapcc.org/findyourcenter.htm

  Kentucky Regional Poison Center
  Medical Towers South, Suite 847
  234 East Gray Street
  Louisville, KY 40202
  Emergency Phone: (800) 222-1222
  http://www.krpc.com/
- Emergency equipment, supplies and medications inventory list with log of monthly reviews/inventory
- Emergency protocols signed by a local physician

*A copy of the Emergency Equipment, Supplies, and Medications list is to be placed on the crash cart, emergency tray or off-site emergency kits with a copy of the current signed protocols.

LHDs may develop modified equipment lists and protocols for alternate service delivery sites. These should, at a minimum, include Benadryl and epinephrine, as well as access to a phone to summon emergency personnel (911).

Modified emergency and anaphylactic shock protocols may be developed locally for off-site service.

MEDICAL EMERGENCIES PROTOCOL*

For various reasons in a LHD setting, a patient may complain of feeling "light headed", "faint", or actually "passing out". This may be as simple as a reaction to certain sensory stimuli, real or perceived pain, or sudden changes in position or as severe as an acute medical condition, such as cardiac or other life threatening conditions.

Condition	Intervention
Syncope/Vasovagal Reaction "light headed – fainting" Response to patient is usually immediate when measures are taken.	• ABC's (Airway, Breathing, Circulation) • Place patient in supine position and loosen clothing. • Elevate lower extremities 20–30 degrees. • Monitor and record BP, pulse and respirations. • Document all findings and actions in patient's medical record. • Question patient after episode about feelings prior to syncope and whether this is an isolated event or "usual response" to certain stimuli. • Advise patient to report this to physician for further investigation.
Suspected Severe, Acute Medical Condition	• ABC's • Call for staff assistance • Maintain **AIRWAY**, provide **CPR** if necessary o Place patient in supine position and loosen clothing. o Monitor and record vital signs. • Call 911 or local Emergency Medical Services immediately (have person not involved in direct care to call).

*Place a copy of this protocol on the crash cart, emergency tray with the Emergency Equipment, Supplies and Medications Inventory List and the Treatment of Anaphylactic Shock Protocol. Modified emergency and anaphylactic shock protocols may be developed locally for off-site service.

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M.D. Signature Date

TREATMENT OF ANAPHYLACTIC SHOCK PROTOCOL*

Definition: Anaphylactic shock is a generalized hypersensitivity and potentially fatal reaction occurring within seconds to minutes after exposure to an antigen. Common causes are penicillin and other antibiotics; biologicals, such as serums, vaccines, tetanus, toxoid; injectable or oral medications; insect bites or stings; foods; allergy extracts; latex exposure; blood transfusions; narcotics, etc. Reactions can range from mild to severe.

<table>
<tr><th>Condition</th><th>Observation/Assessment</th><th>Intervention</th></tr>
<tr><td>MILD REACTION</td><td>• Generalized flush
• Urticaria (hives)
• Sneezing</td><td>
• ABC's
• Monitor pulse and respiration.
• Monitor BP – age 3 years and up
• Continue to observe/ monitor symptoms for change (lessening or worsening).
Dosages for Diphenhydramine hydrochloride (Benadryl) – given orally
Liquid Diphenhydramine hydrochloride (Benadryl) has 12.5 mg per 5 mL
• Adults: 25 mg (10 mL) up to 50 mg (20 mL)
• Child: 1 to 2 mg/kg – given orally
<table>
<tr><td>Wt/Kg:</td><td>11 lbs/5kg</td><td>22 lbs/10 kg</td><td>44 lbs/20 kg</td><td>66 lbs/30 kg or higher</td></tr>
<tr><td>Dose:
1 mg/kg</td><td>2 mL (5 mg)</td><td>4 mL (10 mg)</td><td>8 mL (20 mg)</td><td>12 mL (30 mg)</td></tr>
<tr><td>Up to 2 mg/kg</td><td>Up to 4 mL
(Up to 10 mg)</td><td>Up to 8 mL
(Up to 20 mg)</td><td>Up to 16 mL
(Up to 40 mg)</td><td>Up to 20 mL
(Up to 50 mg)
Max dose</td></tr>
</table>
Dosages for Diphenhydramine hydrochloride (Benadryl) Intramuscular:
• Adult: Benadryl 50 mg IM;
• Child: Benadryl IM, 1 to 2 mg/kg, using the following dosage guidelines:
<table>
<tr><td>Wt/Kg:</td><td>11 lbs/5 kg</td><td>22 lbs/10 kg</td><td>44 lbs/20 kg</td><td>66 lbs/30 kg</td><td>88 lbs/40 kg</td></tr>
<tr><td>Dose:
1 mg/kg</td><td>0.1 mL</td><td>0.2 mL</td><td>0.4 mL</td><td>0.6 mL</td><td>0.8 mL</td></tr>
<tr><td>Up to
2 mg/kg</td><td>Up to
0.2 mL</td><td>Up to
0.4 mL</td><td>Up to
0.8 mL</td><td>Up to 1 mL
Max dose</td><td>Up to 1 mL
Max dose</td></tr>
</table>
• Use Benadryl 50 mg/mL vial to obtain these fractional dosages.
• Wait 12–20 minutes. If improved, dismiss to home with these instructions:
o Adult: Benadryl 50 mg p.o. q 6h x 2 days
o Child > 20 lb.: Benadryl Liquid 5 mg/kg/24 hours (1.25 mg/kg/dose p.o. q 6h) x 2 days
The dose of Diphenhydramine (Benadryl) given for anaphylaxis should be 1 to 2 mg/kg given IM, IV, or orally, with a maximum dose of 50 mg (Harriett Lane Handbook, 17th ed, p. 9).
</td></tr>
</table>

*Place a copy of this protocol on the crash cart, emergency tray with the Emergency Equipment, Supplies and Medications Inventory List and the Treatment of Anaphylactic Shock Protocol. Modified emergency and anaphylactic shock protocols may be developed locally for off-site service.

M.D. Signature Date

TREATMENT OF ANAPHYLACTIC SHOCK PROTOCOL*

(continued)

<table>
<tr><th>Condition</th><th>Observation/Assessment</th><th>Intervention</th></tr>
<tr><td>MODERATE REACTION</td><td>• Mild to moderate wheezing
• Coughing
• Complains of generalized itching, itching throat
• Swelling of lips
• Lack of response to Benadryl</td><td>• ABC's
• Call 911
• Monitor vital signs.
• Continue to observe symptoms for change (lessening or worsening)
• If patient has not improved in 15–20 minutes, OR if symptoms warrant it sooner:
o Give oxygen by mask
o Special instructions** for O2 administration
_____
** Oxygen flow rates, particularly for infants and children, depend upon the equipment available. Local health departments should annotate protocols with the flow rates appropriate for local equipment.
Please see this American Association of Respiratory Care online reference, http://www.aarc.org/resources/protocol_resources/documents/AARCpedO2.pdf

Dosages for Intramuscular epinephrine:
Epinephrine 1:1000 (aqueous): 0.01 mL/kg per dose repeated every 10–20 min.
When body weight is not known, the dosage of epinephrine 1:1000 can be approximated from the subject's age as follows***:
Age: — Usual Dose:
Infant (0–12 mo.) — 0.05–0.1 mL
Children (13 mo.–10 yrs.) — 0.1–0.3 mL (upper arm)
Adolescents (11 yrs.–18 yrs.) — 0.3–0.5 mL (upper arm)
Adult — 0.3 to 0.5 mL
• If symptoms are not resolved, but are not worsening:
o Repeat epinephrine dose q10–20 minutes up to two (2) more times (total of 3 max)
• Advise patient (parent) about the drug or product that caused reaction.
• Advise patient (parent) to report reaction to physician.
• Document all measures taken in patient's medical record and place allergy label on front of patient's medical record.
***See Additional Reference and Alternative Table for Dosages for Intramuscular Epinephrine.</td></tr>
</table>

* Place a copy of this protocol on the crash cart, emergency tray with the Emergency Equipment, Supplies and Medications Inventory List and Medical Emergencies Protocol. Modified emergency and anaphylactic shock protocols may be developed locally for off-site service.

_____

M.D. Signature Date

TREATMENT OF ANAPHYLACTIC SHOCK PROTOCOL*

(continued)

<table>
<tr><th>Condition</th><th>Observation/ Assessment</th><th>Intervention</th></tr>
<tr><td>SEVERE REACTION</td><td>

Anxiety
Shortness of Breath
Severe Wheezing
Restlessness
Headache
Vomiting
Shock
Cyanosis
Confusion
Incontinence
Weak rapid pulse
Hypotension
Unconsciousness

</td><td>

ABC’s
Monitor pulse and respiration, mental status q 1–2 minutes.
Monitor BP – age 3 years and up
Call 911 or local EMS STAT (Have someone not involved in direct patient care make the call).
GIVE OXYGEN BY MASK (Maintain airway – hypoxia can result from hypotension and upper airway edema).

Special Instructions** for O_2 administration _____

**Oxygen flow rates, particularly for infants and children, depend upon the equipment available. Local health departments should annotate protocols with the flow rates appropriate for local equipment. Please see this American Association of Respiratory Care online reference, http://www.aarc.org/resources/protocol_resources/documents/AARCpedO2.pdf

Dosages for Intramuscular Epinephrine:
<table>
<tr><td colspan="2">Epinephrine 1:1000 (aqueous): 0.01 mL/kg per dose
Repeat every 5–10 min. up to 3 times as needed
When body weight is not known, the dosage of epinephrine 1:1000 can be approximated from the subject’s age as follows***:</td></tr>
<tr><th>Age:</th><th>Usual Dose:</th></tr>
<tr><td>Infant (0–12 mo.)</td><td>0.05–0.1 mL</td></tr>
<tr><td>Children (13 mo.–10 yrs.)</td><td>0.1–0.3 mL (upper arm)</td></tr>
<tr><td>Adolescents (11 yrs.–18 yrs.)</td><td>0.3–0.5 mL upper arm)</td></tr>
<tr><td>Adult</td><td>0.3 to 0.5 mL</td></tr>
</table>

Place patient in supine position.
Elevate legs and loosen clothing.
Elevate head, if breathing is difficult.
Maintain accurate emergency flow sheet showing:

Date
Time of occurrence
Vital Signs
Medication(s)
Immediate therapy
Disposition of patient (transfer for further emergency care ASAP)

Send summary of emergency treatment with patient with written assessment of patient’s condition at time of transfer.
Document all measures taken in patient’s medical record and place allergy label on front of patient’s medical record.

***See Additional Reference and Alternative Table for Dosages for Intramuscular Epinephrine.
</td></tr>
</table>

* Place a copy of this protocol on the crash cart, emergency tray with the Emergency Equipment, Supplies and Medications Inventory List and Medical Emergencies Protocol. Modified emergency and anaphylactic shock protocols may be developed locally for off-site service.

M.D. Signature Date

TREATMENT OF ANAPHYLACTIC SHOCK PROTOCOL*

(continued)

Additional Reference and Alternative Table for Dosages for Intramuscular Epinephrine:
http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/95vol21/dr2122ea.html

Epinephrine 1:1000 (aqueous): 0.01 mL/kg per dose Repeat every 5–10 min. up to 3 times as needed **When body weight is not known, the dosage of epinephrine 1:1,000 can be approximated from the subject's age as follows**	
Age	Dose
2 to 6 months*	0.07 mL
12 months*	0.1 mL
18 months* to 4 years	0.15 mL
5 years	0.2 mL
6 - 9 years	0.3 mL
10 - 13 years	0.4 mL
>= 14 years	0.5 mL
* Dosage for children between the ages shown should be approximated, choosing dose volumes intermediate between those shown or the next larger dose, depending on practicability.	

* Place a copy of this protocol on the crash cart, emergency tray with the Emergency Equipment, Supplies and Medications Inventory List and Medical Emergencies Protocol. Modified emergency and anaphylactic shock protocols may be developed locally for off-site service.

_____

M.D. Signature Date

FDA Approval of 2009 Novel H1N1 Vaccine: Summary

FDA approved four vaccines as a strain change to each manufacturer's seasonal influenza vaccine on September 15, 2009. The presentations, age, and dosage specifications listed in the chart below. For more information, as well as the package inserts, visit FDA's website at http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm181950.htm.

Manufacturer	Presentations	Age	Dosage[1]	Type	Package Insert
CSL Limited	-0.5 mL prefilled single-dose syringe (thimerosal free) -5 mL multi-dose vial containing 10 doses (with thimerosal)	Adults 18 years of age and older	-Single 0.5 mL dose	Inactivated virus; intramuscular injection	Link
GlaxoSmithKline[2]	*Awaiting FDA licensure*				
Novartis Vaccines and Diagnostics Limited	-0.5 mL prefilled single-dose syringe (trace thimerosal) -5 mL multi-dose vial (with thimerosal)	Persons 4 years of age and older	-Two 0.5 mL doses approx. 1 month apart for children 4 to 9 -Single 0.5 mL dose for children 10-17 -Single 0.5 mL dose for adults 18 and older	Inactivated virus; intramuscular injection	Link
Sanofi Pasteur Inc.	-0.25 mL prefilled single-dose syringe (thimerosal free) distinguished by pink syringe plunger rod -0.5 mL prefilled single-dose syringe (thimerosal free) -0.5 mL single-dose vial (thimerosal free) -5 mL multi-dose vial (with thimerosal)	Persons 6 months and older	-Two 0.25 mL doses approx. 1 month apart for children 6-35 months of age -Two 0.5 mL doses approx. 1 month apart for children 36 months-9 years -Single 0.5 mL dose for children 10 years and older -Single 0.5 mL dose for adults 18 and older	Inactivated virus; intramuscular injection	Link
MedImmune, LLC	-0.2 mL prefilled single-dose intranasal sprayer	Persons aged 2 to 49 years	-Two 0.2 mL doses approx. 1 month apart for children 2 to 9 -Single 0.2 mL dose for persons 10-49	**LAIV; Intranasal spray**	Link

1 Based on currently available information, which suggests children 6 months to 9 years of age have little or no evidence of protective antibodies to the novel H1N1 virus. It is expected that children 9 years of age and younger should be administered two doses of the vaccine, and that children and adults 10 years of age and older will need one dose. Clinical studies are underway and will provide additional information about the optimal dosage for children.

2 The GlaxoSmithKline H1N1 vaccine has not yet been approved. Based on their licensure for 2009-2010 seasonal influenza vaccine, their H1N1 vaccine can be expected to be an inactivated virus vaccine for adults 18 and older with presentations of 0.5 mL prefilled single-dose syringes (thimerosal free).

ASTHO
September 18, 2009

HANDLING INSTRUCTIONS FOR 2009 H1N1 VACCINE

VACCINE RECEIPT INFORMATION:

Upon receipt of the package, the below steps should be followed:

- Inspect the package and contents for damage.
- Review the temperature monitor card in the package IMMEDIATELY.
- If package is damaged or if there are any concerns about vaccine integrity, please call McKesson Customer Service at 877-TEMP123 (877-836-7123) or your state/local immunization program right away.
- If the contents are in satisfactory condition, receive and process documents in accordance with the following procedures.
    - Count vials/product and place vaccine in monitored refrigerator immediately.
    - If the doses that you have received do not match the packing list, please contact your state/local immunization program right away.

Note: If multiple boxes are received, segregate the vaccine by box. Annotate box and temperature monitors/indicators to identify which temperature monitors belong to which box of vaccine (each box will contain a cold monitor and a warm monitor). The purpose of this is to be able to identify which vials or sprayers were affected if one of the boxes has become compromised in shipment.

VACCINE STORAGE INFORMATION:

- 2009 H1N1 vaccine must be maintained at a temperature of 2 to 8 degrees Celsius (35.6 to 46.4 degrees Fahrenheit). The vaccine must be kept at this temperature at all times.
- The vaccine **MUST NOT BE EXPOSED TO FREEZING TEMPERATURES!** The temperature monitoring device in your refrigerator must have a temperature reading capability to ensure the efficacy of the vaccine prior to administration. Temperature monitoring devices should be appropriately calibrated and methods used for calibration should have stated traceability to National Institute of Standards and Technology (NIST) standards. For more information on NIST traceability, open the following link. http://ts.nist.gov/Traceability/SupplMatls/suppl_matls_for_nist_policy_rev.cfm#FAQ_General. It is the receiving provider's responsibility to maintain proper storage temperature until vaccine administration.
- Any refrigerator used for vaccine storage must be dedicated to storage of biologics (i.e., food or beverages should not be stored in vaccine storage units). Refrigerators should have sufficient usable space to store the largest number of vaccine doses expected at one time without overloading. Vaccines stored in combination refrigerator/freezer units should NEVER be stored in areas directly underneath air vents, in deli-crispers/vegetable bins, or in the doors. Bottles of water can be added to these areas to create thermal mass, thus stabilizing refrigerator temperature. **Dorm-style refrigerator units (freezer and refrigerator with shared exterior door) provide poor temperature control and often freeze vaccines, therefore should not be used to store vaccines any longer than the length of a clinic for a particular clinical day (i.e., vaccines should not be stored overnight in dorm-style refrigerators).**
- The refrigerator storage unit must be electronically alarmed or manually monitored; temperatures should be recorded at a minimum of every 12 hours.
- A record of these readings should be maintained at the location of the vaccine storage unit, for example on the door. Refer to the Centers for Disease Control and Prevention's Vaccine Storage and Handling Toolkit for further guidance. This site can be accessed at the following link: http://www2a.cdc.gov/vaccines/ed/shtoolkit/pages/resources.htm.

Skills Validation For
Intramuscular H1N1 Influenza Immunization Administration (Adult)

Measurement Criteria	Met	Not Met
1. Verifies correct medication (verifes the age appropriateness)		
2. Verifies correct dosage		
3. Utilizes 22-23 gauge x 1 inch as standard or 22-23 gauge x 1 ½ inch needle as adjustment needle length for larger patients to facilitate an intramuscular injection		
4. Able to correctly describe activation of safety device to prevent needlestick		
5. Sanitizes hands		
6. Verifies that receiving patient is not allergic to egg or has other contraindication to immunization		
7. Identifies deltoid muscle and is able to identify the triangular muscle region appropriate for use in the injection. (May use vastus lateralis in any aged individual)		
8. Insures that there is no constricting clothing around upper arm area		
9. Helps patient relax arm to decrease muscle tension and resultant soreness. (Positions child appropriately).		
10. Cleanses injection area with alcohol swab		
11. Uses “press and spread” method to insure an intramuscular injection in the deltoid muscle		
12. Aspirates prior to injection		
13. After injection, gently massages area and applies band-aid (if available and applicable)		
14. Activates safety device and disposes of device and syringe in appropriate sharps container		
15. Instructs patient to move arm and periodically massage injection area during the next 24-48 hours to prevent soreness		
16. Provides patient education information regarding influenza vaccine		
17. Maintains personal protective equipment and emergency pharmaceutical agents within easy reach		
18. Able to verbally demonstrate appropriate use of epinephrine pen injector		
19. Able to verbally demonstrate documentation requirements		

Validation for:_____ Date_____

Validation verified by:_____ Date_____

08-09

Needle Length and Injection Site for Inactivated Influenza Vaccine

Inactivated influenza vaccine must be administered by the <u>intramuscular route</u> only

Birth through 18 years of age		
Age	**Needle Length**	**Injection Site**
Infant 6 – 12 months	1” (25 mm)	Anterolateral thigh
Toddler 1 - 2 years	1” - 1 ¼” (25-32 mm) 5/8”* - 1” (16-25 mm)	Anterolateral thigh+ Deltoid muscle of the arm
Child/adolescent 3 through 18 years	5/8”* - 1” (16-25 mm) 1” - 1 ¼” (25-32 mm)	Deltoid muscle of the arm+ Anterolateral thigh
19 years of age and older		
Sex/weight	**Needle Length**	**Injection Site**
Male and female less than 130 lbs (60 kg)	1” (25 mm)	Deltoid muscle of the arm
Female 130 - 200 lbs (60-90 kg)	1” - 1½” (25-38 mm)	Deltoid muscle of the arm
Male 130 – 260 lbs (60-118 kg)	1½” (38 mm)	Deltoid muscle of the arm
Female more than 200 lbs (90 kg)	1½” (38 mm)	Deltoid muscle of the arm
Male more than 260 lbs (118 kg)	1½” (38 mm)	Deltoid muscle of the arm

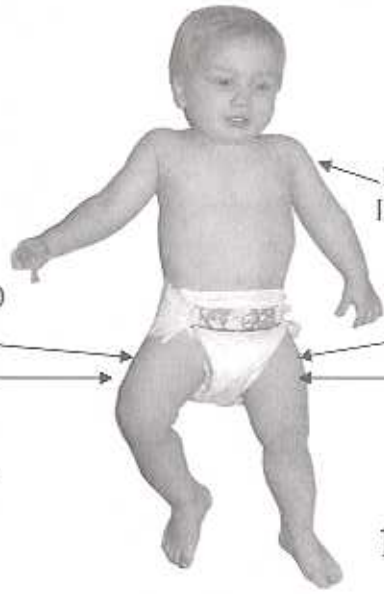
*A 5/8” needle may be used only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

+Preferred site.

Adapted from *General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices. MMWR* 2006;55(RR-15). September 2009.

Giving All the Doses Including Influenza Vaccine (TIV)

Using Pediarix™ (DTaP/HepB/IPV) and ProQuad® (MMR/Var)



MMRV (SC)
[ProQuad®]

DTaP/Hep B/IPV (IM)
[Pediarix™]

PCV7 (IM)

HIB (IM)

Influenza (IM)
[TIV]

Pediarix™ can only be used for the primary series; DO NOT use for 4th or 5th dose of DTaP or 4th dose of IPV.

For children 12 thru 4 years of age

- TIV Dosages:
  6-35 mos 0.25 mL
  3-8 yrs 0.5 mL
- 2 doses (4 weeks apart) are recommended for children 6 mo thru 8 yrs receiving any flu vaccine for the first time
- Children 6 mo-8 yrs who received influenza vaccine for the first time **during the previous influenza season**, and got only one dose, should receive two doses this season separated by 4 weeks

Skills Validation For
Intranasal H1N1 Influenza Immunization Administration

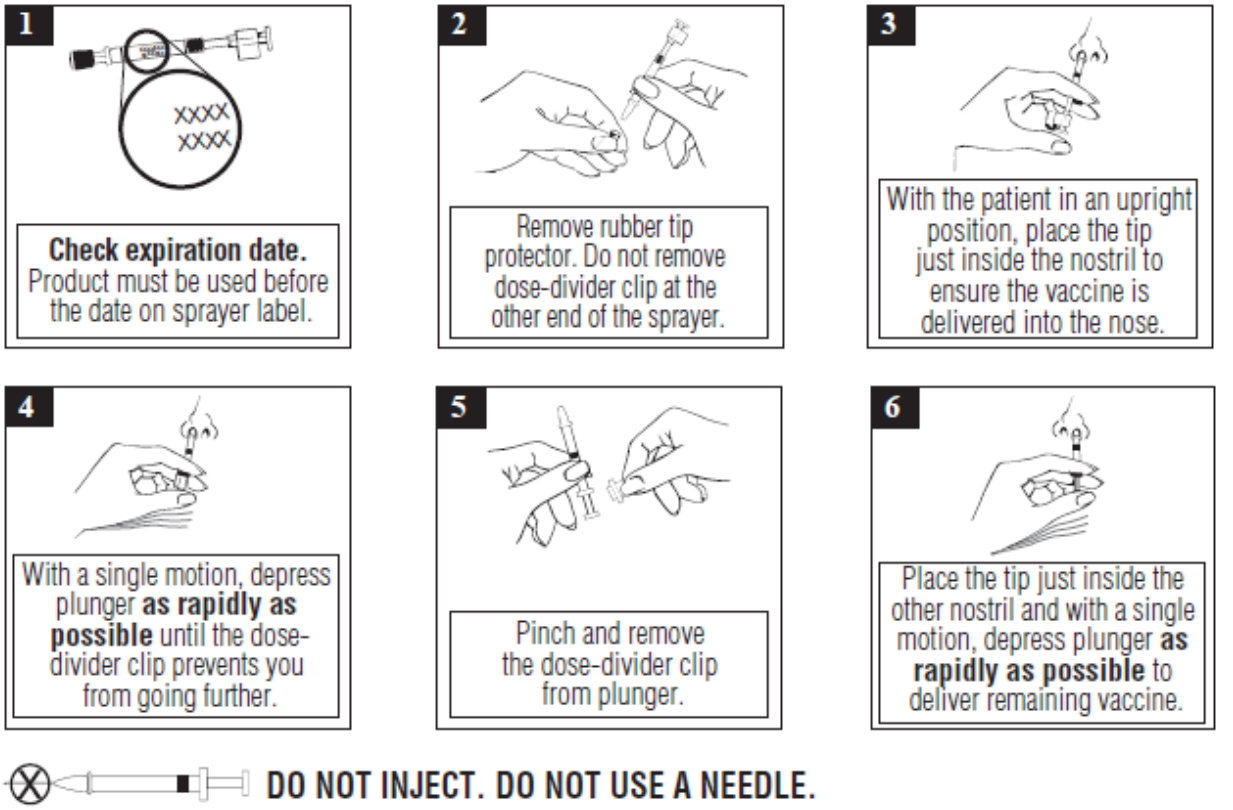
Measurement Criteria	Met	Not Met
1. Verifies correct medication (intranasal influenza vaccine for the correct flu season)		
2. Verifies correct dosage in syringe and ensures syringe has not been activated		
3. Performs hand hygiene using alcohol-based hand rub or soap and water hand wash. Helps vaccine recipient perform hand hygiene if he/she is self-administering		
4. Removes cap of syringe in a manner that minimizes the opportunity for contamination		
5. Provides vaccine recipient with tissue		
6. Inserts tip of syringe into the nares of the vaccine recipient or observes vaccine recipient as he/she inserts syringe into nares		
7. Administers vaccine into one nare of the recipient ensuring that the entire dose/portion is administered		
8. Instructs vaccine recipient to use tissue if needed		
9. Removes clip from syringe so second portion of the dose can be administered		
10. Inserts tip of syringe into the other nare of the vaccine recipient or observes vaccine recipient as he/she inserts syringe into nare		
11. Administers vaccine into the nare of the recipient ensuring that the entire remaining dose/portion is administered		
12. Instructs vaccine recipient to use tissue, if needed		
13. Disposes of syringe in regulated waste container and other items into the general trash		
14. Completes documentation		
15. Provides patient education regarding vaccine side effects and contact numbers for emergency		
16. Able to verbally demonstrate appropriate use of epinephrine pen injector		
17. Able to demonstrate documentation as required		

Validation for:_____ Date_____

Validation verified by:_____ Date_____

08-09

Figure 1



3 DOSAGE FORMS AND STRENGTHS

Pre-filled, single-dose intranasal sprayer containing 0.2 mL suspension *[See Description (11)]*.

4 CONTRAINDICATIONS

4.1 Hypersensitivity

Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal is contraindicated in individuals with a history of hypersensitivity, especially anaphylactic reactions, to eggs, egg proteins, gentamicin, gelatin, or arginine or with life-threatening reactions to previous influenza vaccinations.

CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR PUBLIC HEALTH

Steven L. Beshear
Governor

275 East Main Street, HS1GWA
Frankfort, Kentucky 40621-0001
502-564-3970 502-564-9377 fax

Janie Miller
Secretary

October 13, 2009

Dear Healthcare Provider:

As a healthcare provider, you can help monitor the safety of vaccines by promptly and accurately reporting any clinically significant adverse event that occurs following vaccination to the Vaccine Adverse Event Reporting System (VAERS). Clinically significant adverse events are those events that are of concern to you or your vaccinated patients or their caregivers. Anyone can report to VAERS but vaccinated patients or their caregivers are encouraged to seek the help of their health care provider in filling out a VAERS form. Please report clinically significant adverse events after vaccination, whether or not the vaccine was administered in your practice, and even if you are not sure if the vaccine caused the adverse event.

VAERS is a U.S. vaccine safety surveillance system, co-managed by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS is the front-line monitoring system for collecting and analyzing voluntary reports of adverse events following vaccination. CDC and FDA analyze VAERS reports to identify potential vaccine safety concerns that may need further study or public health action.

There are three ways to report to VAERS:
1) Submit online via a secure website at http://vaers.hhs.gov/esub/index
2) Fax a completed VAERS form to 877-721-0366, or
3) Mail a completed VAERS form to VAERS, P.O. Box 1100, Rockville, MD 20849-1100.

In addition, to ensure that the Kentucky Immunization Program is made aware of vaccine adverse events occurring in Kentucky in a timely manner, please make a copy of the completed VAERS form and mail it to:

Kentucky Department for Public Health
Immunization Program
275 East Main Street, HS2E-B
Frankfort, KY 40621

A VAERS form may be downloaded from the VAERS website at http://vaers.hhs.gov/esub/index. Alternatively, you may request a VAERS form by sending an email to info@vaers.org, by calling toll-free 800-822-7967, or by sending a faxed request to 877-721-0366. For additional information on VAERS or vaccine safety, visit the VAERS website at vaers.hhs.gov/index or call 800-822-7967.

When submitting a report to VAERS, please include as much information requested on the form as possible to assist VAERS staff with analysis and follow-up of the adverse event. For example, please include information about vaccination location, date, vaccine type, lot number and dose. The form also includes a space to provide contact information for the person reporting the adverse event.

Influenza vaccination record cards will be given to people who receive 2009 influenza A (H1N1) monovalent vaccine. The information on this card may be helpful in completing a VAERS report for an adverse event that occurred after 2009 H1N1. It also can include information on seasonal influenza vaccines. http://www.cdc.gov/h1n1flu/vaccination/slv/pdf/h1n1vaxrecord.pdf

By reporting vaccine adverse events to VAERS, the public health system will continue to be able to rapidly detect potential risks for serious or new adverse events after vaccination. This knowledge facilitates improvements in the safety of vaccines. Thank you in advance for your participation. Together we can ensure that vaccination continues to be as safe as possible.

Sincerely,

Kraig E. Humbaugh, M.D., M.P.H.
Director, Division of Epidemiology and Health Planning
Kentucky Department for Public Health

CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR PUBLIC HEALTH

2009 H1N1 Influenza (Swine Flu)
Oseltamivir Pediatric Treatment
September 28, 2009

Dear Kentucky Clinician:

This letter is to provide updated clinician guidance for the pediatric prescription of oseltamivir (Tamiflu) for H1N1 influenza treatment. The Kentucky Department for Public Health has received reports of spot shortages of pre-packaged pediatric oseltamivir suspension and is predicting the situation to worsen. Fortunately, a supply of adult capsules is commercially available.

Clinicians are advised to prescribe this medication in mg (milligrams) rather than mL (milliliters) or tsp (teaspoons).

All pharmacists are able to compound suspensions on-site from available capsule supplies in case of a shortage of pre-packaged suspensions. Pharmacies do not have to be a compounding facility since this process is not a sterile procedure. Clinicians are also advised to write the following statement on prescriptions for suspensions: "May be substituted with compounded suspensions."

Thank you for your willingness to work with us to appropriately address this situation. Information can be found at KDPH's Health Alerts website: http://healthalerts.ky.gov and the CDC website: http://www.cdc.gov/h1n1flu.

CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR PUBLIC HEALTH

2009 H1N1 Influenza (Swine Flu)
Oseltamivir Pediatric Treatment
September 28, 2009

KEY POINTS

Prescribe in "MG – MILLIGRAMS"
Use mg (milligrams) rather than mL (milliliters) or tsp (teaspoons).

Prescribe with "MAY SUBSTITUTE WITH COMPOUNDED SUSPENSION"
All pharmacists are able to compound from capsules on-site in case of suspension shortages.

Pediatric Treatment Dosages

Age	Body Weight (kg)	Body Weight (lb)	Dose for 5 Days
<3 months	not applicable	not applicable	12 mg twice daily
3-5 months	not applicable	not applicable	20 mg twice daily
6-11 months	not applicable	not applicable	25 mg twice daily
1-2 years	≤15	≤33	30 mg twice daily
3-5 years	>15 to 23	>33 to 51	45 mg twice daily
6-9 years	>23 to 40	>51 to 88	60 mg twice daily
10-12 years	>40	>88	75 mg twice daily
13-17 years	not applicable	not applicable	75 mg twice daily

Example: 3.5 year-old weighing 17kg

Rx

OSELTAMIVIR SUSPENSION 45MG
TWICE DAILY BY MOUTH x 5 DAYS
MAY SUBSTITUTE WITH COMPOUNDED SUSPENSION

CDC Documents Available Online

- Oseltamivir Dosing for H1N1: http://www.cdc.gov/h1n1flu/eua/pdf/tamiflu-hcp.pdf
- Antiviral Dosing for H1N1: http://www.cdc.gov/h1n1flu/eua/
- Antiviral Prescribing for H1N1: http://www.cdc.gov/h1n1flu/recommendations.htm

Centers for Disease Control and Prevention
Your Online Source for Credible Health Information

Interim Guidance for 2009 H1N1 Flu (Swine Flu): Taking Care of a Sick Person in Your Home

September 24, 2009 10:00 AM ET

This document has been updated in accordance with the CDC Recommendations for the Amount of Time Persons with Influenza-Like Illness Should be Away from Others . This document provides interim guidance and will be updated as needed.

2009 H1N1 flu virus infection (formerly known as swine flu) can cause a wide range of symptoms, including fever, cough, sore throat, runny or stuffy nose, body aches, headache, chills and fatigue. Some people may also have vomiting and diarrhea. People may be infected with the flu, including 2009 H1N1, and have respiratory symptoms without a fever. Like seasonal flu, 2009 H1N1 flu in humans can vary in severity from mild to severe. Severe disease with pneumonia, respiratory failure and even death is possible with 2009 H1N1 flu infection. Certain groups might be more likely to develop a severe illness from 2009 H1N1 flu infection, such as pregnant women and persons with chronic medical conditions. Sometimes bacterial infections may occur at the same time as or after infection with influenza viruses and lead to pneumonias, ear infections, or sinus infections.

The following information can help you provide safer care at home for sick persons during a flu outbreak or flu pandemic.

How Flu Spreads

The main way that influenza viruses are thought to spread is from person to person in respiratory droplets of coughs and sneezes. This can happen when droplets from a cough or sneeze of an infected person are propelled through the air and deposited on the mouth or nose of people nearby. Influenza viruses may also be spread when a person touches respiratory droplets on another person or an object and then touches their own mouth or nose (or someone else's mouth or nose) before washing their hands.

People with 2009 H1N1 flu who are cared for at home should:

- check with their health care provider about any special care they might need if they are pregnant or have a health condition such as diabetes, heart disease, asthma, or emphysema
- check with their health care provider about whether they should take antiviral medications
- keep away from others as much as possible. This is to keep from making others sick. Do not go to work or school while ill
- stay home for at least 24 hours after fever is gone, except to seek medical care or for other necessities. (Fever should be gone without the use of a fever-reducing medicine.)
- get plenty of rest
- drink clear fluids (such as water, broth, sports drinks, electrolyte beverages for infants) to keep from being dehydrated
- cover coughs and sneezes. Wash hands often with soap and water. If soap and water are not available, use an alcohol-based hand rub.*
- wear a facemask – if available and tolerable – when sharing common spaces with other household members to help prevent spreading the virus to others. This is especially important if other household members are at high risk for complications from influenza. For more information, see the Interim Recommendations for Facemask and Respirator Use
- be watchful for emergency warning signs (see below) that might indicate you need to seek medical attention.

TOP

Medications to Help Lessen Symptoms of the Flu

Check with your healthcare provider or pharmacist for correct, safe use of medications

Antiviral medications can sometimes help lessen influenza symptoms, but require a prescription. Most people do not need these antiviral drugs to fully recover from the flu. However, persons at higher risk for severe flu complications, or those with severe flu illness who require hospitalization, might benefit from antiviral medications. Antiviral medications are available for persons 1 year of age and older. Ask your health care provider whether you need antiviral medication.

Influenza infections can lead to or occur with bacterial infections. Therefore, some people will also need to take antibiotics. More severe or prolonged illness or illness that seems to get better, but then gets worse again may be an indication that a person has a bacterial infection. Check with your health care provider if you have concerns.

Warning! Do ***not*** give aspirin (acetylsalicylic acid) to children or teenagers who have the flu; this can cause a rare but serious illness called Reye's syndrome. For more information about Reye's syndrome, visit the National Institute of Health website □.

- Check ingredient labels on over-the-counter cold and flu medications to see if they contain aspirin.
- Children 5 years of age and older and teenagers with the flu can take medicines ***without*** aspirin, such as acetaminophen (Tylenol®) and ibuprofen (Advil®, Motrin®, Nuprin®), to relieve symptoms.
- Children younger than 4 years of age should **NOT** be given over-the-counter cold medications without first speaking with a health care provider.
- The safest care for flu symptoms in children younger than 2 years of age is using a cool-mist humidifier and a suction bulb to help clear away mucus.
- Fevers and aches can be treated with acetaminophen (Tylenol®) or ibuprofen (Advil®, Motrin®, Nuprin®) or nonsteroidal anti-inflammatory drugs (NSAIDS). Examples of these kinds of medications include:

Generic Name	Brand Name(s)
Acetaminophen	Tylenol®
Ibuprofen	Advil®, Motrin®, Nuprin®
Naproxen	Aleve

- Over-the-counter cold and flu medications used according to the package instructions may help lessen some symptoms such as cough and congestion. Importantly, these medications will not lessen how infectious a person is.
- Check the ingredients on the package label to see if the medication already contains acetaminophen or ibuprofen before taking additional doses of these medications—don't double dose! Patients with kidney disease or stomach problems should check with their health care provider before taking any NSAIDS.

Check with your health care provider or pharmacist if you are taking other over-the-counter or prescription medications not related to the flu.For more information on products for treating flu symptoms, see the FDA website .

When to Seek Emergency Medical Care

Get medical care right away if the sick person at home:

- has difficulty breathing or chest pain

- has purple or blue discoloration of the lips
- is vomiting and unable to keep liquids down
- has signs of dehydration such as dizziness when standing, absence of urination, or in infants, a lack of tears when they cry
- has seizures (for example, uncontrolled convulsions)
- is less responsive than normal or becomes confused

TOP

Steps to Lessen the Spread of Flu in the Home

When providing care to a household member who is sick with influenza, the most important ways to protect yourself and others who are not sick are to:

- keep the sick person away from other people as much as possible (see "placement of the sick person") especially others who are at high risk for complications from influenza
- remind the sick person to cover their coughs, and clean their hands with soap and water often. If soap and water are not available, they should use an alcohol-based hand rub*, especially after coughing and/or sneezing
- have everyone in the household clean their hands often, using soap and water (or an alcohol-based hand rub*, if soap and water are not available). Children may need reminders or help keeping their hands clean
- ask your health care provider if household contacts of the sick person—particularly those contacts who may be pregnant or have chronic health conditions—should take antiviral medications such as oseltamivir (Tamiflu®) or zanamivir (Relenza®) to prevent the flu
- If you are in a high risk group for complications from influenza, you should attempt to avoid close contact (within 6 feet) with household members who are sick with influenza. If close contact with a sick individual is unavoidable, consider wearing a facemask or respirator, if available and tolerable. Infants should not be cared for by sick family members. For more information, see the Interim Recommendations for Facemask and Respirator Use

Placement of the sick person

- Keep the sick person in a room separate from the common areas of the house. (For example, a spare bedroom with its own bathroom, if that's possible.) Keep the sickroom door closed.
- Unless necessary for medical care or other necessities, people who are sick with an influenza-like-illness should stay home and keep away from others as much as possible, including avoiding travel, for at least 24 hours after fever is gone except to get medical care or for other necessities. (Fever should be gone without the use of a fever-reducing medicine). This is to keep from making others sick. Children, especially younger children, might potentially be contagious for longer periods.
- If persons with the flu need to leave the home (for example, for medical care), they should wear a facemask, if available and tolerable, and cover their nose and mouth when coughing or sneezing
- Have the sick person wear a facemask – if available and tolerable – if they need to be in a common area of the house near other persons.
- If possible, sick persons should use a separate bathroom. This bathroom should be cleaned daily with household disinfectant (see below).

Protect other persons in the home

- The sick person should not have visitors other than caregivers. A phone call is safer than a visit.
- If possible, have only one adult in the home take care of the sick person. People at increased risk of severe illness from flu should not be the designated caretaker, if possible.
- If you are in a high risk group for complications from influenza, you should attempt to avoid close contact (within 6 feet) with household members who are sick with influenza. If close contact with a sick individual is unavoidable, consider wearing a facemask or respirator, if available and tolerable. For more

information, see the Interim Recommendations for Facemask and Respirator Use.

- Avoid having pregnant women care for the sick person. (Pregnant women are at increased risk of influenza-related complications and immunity can be suppressed during pregnancy).
- Avoid having sick family members care for infants and other groups at high risk for complications of influenza.
- All persons in the household should clean their hands with soap and water frequently, including after every contact with the sick person or the person's room or bathroom.
- Use paper towels for drying hands after hand washing or dedicate cloth towels to each person in the household. For example, have different colored towels for each person.
- If soap and water are not available, persons should use an alcohol-based hand rub.*
- If possible, consideration should be given to maintaining good ventilation in shared household areas (e.g., keeping windows open in restrooms, kitchen, bathroom, etc.).
- Antiviral medications can be used to prevent the flu, so check with your health care provider to see if some persons in the home should use antiviral medications.

If you are the caregiver

- Avoid being face-to-face with the sick person.
- When holding small children who are sick, place their chin on your shoulder so that they will not cough in your face.
- Clean your hands with soap and water after you touch the sick person or handle used tissues, or laundry. If soap and water are not available, use an alcohol-based hand rub*
- Talk to your health care provider about taking antiviral medication to prevent the caregiver from getting the flu.
- If you are at high risk of influenza associated complications, you should not be the designated caretaker, if possible.
- If you are in a high risk group for complications from influenza, you should attempt to avoid close contact (within 6 feet) with household members who are sick with influenza. Designate a person who is not at high risk of flu associated complications as the primary caretaker of household members who are sick with influenza, if at all possible. If close contact with a sick individual is unavoidable, consider wearing a facemask or respirator, if available and tolerable. For more information, see the Interim Recommendations for Facemask and Respirator Use
- **Monitor yourself and household members for flu symptoms and contact a telephone hotline or health care provider if symptoms occur.**

Using Facemasks or Respirators

- Avoid close contact (less than about 6 feet away) with the sick person as much as possible.
- If you must have close contact with the sick person (for example, hold a sick infant), spend the least amount of time possible in close contact and try to wear a facemask (for example, surgical mask) or N95 disposable respirator.
- An N95 respirator that fits snugly on your face can filter out small particles that can be inhaled around the edges of a facemask, but compared with a facemask it is harder to breathe through an N95 mask for long periods of time. More information on facemasks and respirators can be found at H1N1 Flu (Swine Flu) website.
- Facemasks and respirators may be purchased at a pharmacy, building supply or hardware store.
- Wear an N95 respirator if you help a sick person with respiratory treatments using a nebulizer or inhaler, as directed by their doctor. Respiratory treatments should be performed in a separate room away from common areas of the house when at all possible.
- Used facemasks and N95 respirators should be taken off and placed immediately in the regular trash so they don't touch anything else.
- Avoid re-using disposable facemasks and N95 respirators, if possible. If a reusable fabric facemask is used, it should be laundered with normal laundry detergent and tumble-dried in a hot dryer.
- After you take off a facemask or N95 respirator, clean your hands with soap and water or an alcohol-based hand sanitizer.

- For more information, see the Interim Recommendations for Facemask and Respirator Use

TOP

Household Cleaning, Laundry, and Waste Disposal

- Throw away tissues and other disposable items used by the sick person in the trash. Wash your hands after touching used tissues and similar waste.
- Keep surfaces (especially bedside tables, surfaces in the bathroom, and toys for children) clean by wiping them down with a household disinfectant according to directions on the product label.
- Linens, eating utensils, and dishes belonging to those who are sick do not need to be cleaned separately, but importantly these items should not be shared without washing thoroughly first.
- • Wash linens (such as bed sheets and towels) by using household laundry soap and tumble dry on a hot setting. Avoid “hugging” laundry prior to washing it to prevent contaminating yourself. Clean your hands with soap and water right after handling dirty laundry. If soap and water are not available, use an alcohol-based hand rub.*
- Eating utensils should be washed either in a dishwasher or by hand with water and soap.

For More Information

The Centers for Disease Control and Prevention (CDC) Hotline (1-800-CDC-INFO) is available in English and Spanish, 24 hours a day, 7 days a week.

TOP

Page last reviewed September 24, 2009 10:00 AM ET
Page last updated September 24, 2009 10:00 AM ET
Content source: Centers for Disease Control and Prevention

Centers for Disease Control and Prevention 1600 Clifton Rd. Atlanta, GA 30333, USA
800-CDC-INFO (800-232-4636) TTY: (888) 232-6348, 24 Hours/Every Day - cdcinfo@cdc.gov

Centers for Disease Control and Prevention
Your Online Source for Credible Health Information

2009 H1N1 Influenza Vaccine and Seniors

September 30, 2009, 2:30 PM ET

Why aren't people 65 and older recommended to get early doses of 2009 H1N1 vaccine?

There are two main reasons why people age 65 and older are not included in the groups recommended to get the initial doses of 2009 H1N1 vaccine:

1. People age 65 and older are least likely to get sick with this virus, and,
2. There will be limited amounts of vaccine available at first, so the first doses are recommended to go to those who are most likely to get infected and become very ill.

There has been very little 2009 H1N1 illness in people 65 and older since the 2009 H1N1 virus emerged. This has been true both in the United States and in the Southern Hemisphere during their flu season. Studies of who is most likely to be infected with 2009 H1N1 show that people 65 and older are the **least likely** to get sick with this virus. (One analysis showed that only 1.3 people for every 100,000 people 65 and older are had been infected with 2009 H1N1. This is compared to 26.7 per 100,000 of those 5 years to 24 years of age and 22.9 per 100,000 in those younger than 5 years old. Rates among younger persons were 15 to 20 times higher. This has been true both in the United States and in the Southern Hemisphere during their flu season.) Laboratory tests on blood samples indicate that older people likely have some pre-existing immunity to the 2009 H1N1 flu virus.

Because there has been so little 2009 H1N1 illness in people 65 and older, the Advisory Committee on Immunization Practices (ACIP) recommended that CDC and immunization programs focus on getting the first doses of 2009 H1N1 vaccine to those people who are more likely to get infected with the 2009 H1N1 flu virus. This includes all children and young adults 6 months through 24 years old, pregnant women, and adults 25 through 64 years of age who have health conditions associated with higher risk of medical complications from flu**. In addition, the 2009 H1N1 vaccine is prioritized for** people who live with or care for children younger than 6 months of age, and health care and emergency medical services personnel with direct patient contact. Persons 65 and older are a high priority for seasonal vaccine, just as they have been in past years. Please visit http://www.cdc.gov/h1n1flu/vaccination/acip.htm to see a summary of ACIP's 2009 H1N1 vaccine recommendations.

Will people age 65 years and older be able to get the 2009 H1N1 vaccine this season?

Yes. The U.S. government has purchased 250 million doses of 2009 H1N1 vaccine, so anyone who wants to get the vaccine will have the opportunity to do so. While people 65 and older are not included in the groups recommended to get the earliest doses of vaccine, they can get the 2009 H1N1 influenza vaccine as soon as the high risk groups have had the opportunity to be vaccinated. Some communities and providers will offer the 2009 H1N1 vaccine to people 65 and over sooner than others, depending on how quickly they meet the needs of the initial prioritized populations. While the early doses of 2009 H1N1 vaccine are being given to those in high risk groups, CDC's priority for people 65 and older is to have them get their seasonal flu vaccine first, and to seek medical advice quickly if they develop flu-like symptoms this season. This will determine whether they need medical evaluation and possible treatment with antiviral medications.

Should people age 65 and older get the regular flu vaccine this year?

Yes. CDC's priority for people 65 and older is to have them get their regular, or "seasonal," flu vaccine as soon as possible while we are waiting for more doses of the 2009 H1N1 vaccine. Seasonal flu viruses are expected to

circulate along with 2009 H1N1 viruses this season. People age 65 and older are at increased risk for complications from seasonal influenza compared to younger people and are recommended for annual seasonal flu vaccines. This year is no exception.

What should people age 65 and older do if they feel like they have the flu?

People age 65 and older should seek medical advice quickly if they develop flu symptoms this season to see whether they might need medical evaluation and possible treatment with antiviral medications. People 65 and older are prioritized to get antiviral drugs if they become sick with the flu according to CDC's antiviral guidance this season.

Why are people 65 and older prioritized for antiviral treatment if they get sick with the flu, but they are not in one of the early groups prioritized to get 2009 H1N1 vaccine?

People 65 and older are the least likely to be infected with 2009 H1N1 flu, but, if they become infected, they are more likely than people in some other groups to develop serious complications from their illness. That is why people 65 years and older are prioritized for treatment with antiviral drugs this season if they do become sick.

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Department of Public Health Training Matrix for Disaster Preparedness Plans
September 2009

Health Department:	TRAIN #	Contact Hours	MRC-MEDICAL	MRC-NON MEDICAL	Date Completed	Core Competency met
Strategic National Stockpile						
☐ SNS 100 Introduction, Terms & Concepts Introduction to the Department Operations Center (DOC)	1010328	1.0				
☐ SNS 110 Point of dispensing (POD) Staff Introductory Level Training SNS 120 Distribution Node (DN) Staff Introductory Level Training	1010329	1.0				
☐ SNS 210 Dispensing (Level 2 Jurisdictional)	Under development					
☐ SNS 220 Distribution Node (Level 2 Jurisdictional)	Under development					
☐ SNS 220 Distribution Node (Level 2 Jurisdictional)	Under development					
☐ SNS-300 Management Considerations	Under development					
☐						
Cold Chain Management						
☐ Under Development						
Continuity of Operations Plan (COOP)						
☐ COOP IS-00546	1005511	0.1				
☐ COOP IS-00548	1018388	0.4				
☐ COOP Module 4	1014584					
Epi Rapid Response Team						
☐ E is for Epi Session I, Part I: Epidemiology in the Context of Public Health	1004036					
☐ E is for Epi, Session I, Part II: Profile and Practice of Epidemiology	1004037					
☐ E is for EPI, Session II, Part I: An Epidemiologist's Toolkit	1004038					
☐ E is for Epi, Session II, Part II: Data & Technology "Tools"	1004039					
☐ E is for Epi, Session III, Part I: Descriptive and Analytic Epidemiology	1004040					
☐ E is for Epi, Session III, Part II: Hypotheses and Study Designs	1004041					
☐ E is for Epi, Session IV, Part I: Surveillance	1004046					

☐ **E is for Epi, Session IV, Part II: Federal Public Health Surveillance**	1004048					
☐ **E is for Epi, Session V, Part I: Epidemiology Specialties Applied – Disaster & Environmental Epidemiology**	1004050					
☐ **E is for Epi, Session V, Part II: Epidemiology Specialties Applied**	1004051					
Homeland Security Exercise and Evaluation Program						
☐ **An Introductions to Exercises IS-120**	1011646	0.5				

Command and Management						
☐ **FEMA NIMS IS 700.a***	1016070					
☐ **FEMA Incident Command IS 100.a**	1016067	0.3				
☐ **FEMA Single Resource, Incident Action Plan IS 200**	1005012					
☐ **FEMA National Response Framework (NRF) IS 800b**	1011882					
☐ **FEMA ICS-300 Intermediate ICS for Expanding Incidents**	Face-to-Face only					
☐ **FEMA ICS-400 Advanced Incident Management System**	Face-to-Face only					
Mass Vaccination Clinics						
☐ **SNS 100 Introduction, Terms & Concepts Introduction to the Department Operations Center (DOC)**	1010328					
☐ **SNS 110 Point of dispensing (POD) Staff Introductory Level Training**	1009414					
☐ **SNS 200 Planning Considerations**	1015266					
☐ **SNS 220 Distribution Node**	1009416					
Risk Communications						
☐ **Crisis and Emergency Risk Communications: Best Practices**	1017722		Web Cast			
☐ **Crisis Management**	1012384		Web Cast			
☐ **MRC Risk Communication**	1009111					

*This module needs updated Test

COURSE DESCRIPTIONS

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ICS-100 Introduction to ICS

Course Description: This course is designed to give an introduction to the principles, common terminology and position responsibilities when responding to an event using the Incident Command System. The course specifically discusses major ICS functions and their primary responsibilities, ICS organizational units, span of control, major incident facilities and the function of each, what an Incident Action Plan is and how it is used, and the common responsibilities associated with incident assignments from the Federal disaster response workforce perspective. TRAIN course ID# 1014646

Strategic National Stockpile Team

SNS 100 Introduction, Terms & Concepts/Introduction to the Department Operations Center (DOC)

This first section of this introductory level training will introduce the participant to the Strategic National Stockpile, federal repository of pharmaceuticals and medical supplies for emergencies/disasters. Objectives: Define the Strategic National Stockpile (SNS), describe the concept for communities to receive the SNS, identify SNS contents. Estimated time of completion for this section: 30 minutes.

The Department Operations Center (DOC) section will introduce the participant to the concept of managing an agencies response under the direction of a DOC and how the DOC fits into overall community response. Objectives: State the purpose and function of the Department Operations Center (DOC), describe the difference between the DOC and the Emergency Operations Center (EOC), describe the Incident Command Structure of a DOC and the duties of the staff, describe the operational phases of a DOC activation, state the requirements for DOC location, activation, operations, and deactivation, list the documentation requirements of DOC operations, including After Action Reports (AAR). Estimated time of completion for this module: 30 minutes.

SNS 110 Point of Dispensing (POD) Staff Introductory Level Training / SNS 120 Distribution Node (DN) Staff Introductory Level Training

This section will introduce participants to Points of Dispensing (POD) Operations. The Point of Distribution (POD) module will introduce the participant to the concepts associated with distributing emergency supplies to communities. Objectives: Describe the purpose of a Point of Dispensing (POD), discuss when it may be necessary to open a POD, define the goal of a POD, recommend an Incident Command Structure (ICS) for the organization of POD staff, recommend minimum job functions for a POD, recommend job action sheets (JAS) for POD functions, identify a possible POD flow diagram. Estimated time of completion for this module: 30 minutes.

This section will introduce participants to the Distribution Node (DN) and its function in the distribution of emergency supplies. The Distribution Node (DN) module provides awareness level training on the receipt, storage, and distribution of SNS assets. Objectives: Describe a Distribution Node (DN), list events that could cause a DN to be utilized, summarize the purpose of a DN, describe job functions in a DN. Estimated time of completion for this module: 30 minutes.

SNS 210 Dispensing (Level 2 Jurisdictional)

This course is currently under development and will be available soon.

SNS 220 Distribution Node (Level 2 Jurisdictional)

This course is currently under development and will be available soon.

SNS-300 Management Considerations

This course is currently under development and will be available soon

Kentucky Department of Public Health MRC Risk Communication

This module describes the MRC member's communication role(s) and processes with response partners, media, general public and others. This awareness level course defines Risk Communication, "The Seven Cardinal Rules of Risk Communication" and "The 10 Deadly Sins of Communication". This course should take approximately 30 minutes to complete. Objectives: The overall objective of risk communications is to establish and maintain the public confidence by providing information, identify the purpose of Risk Communication, define the role of the Public Information Officer, list the 10 Deadly Sins of communication.

IS-200 Single Resources, Incident Action Plan

ICS 200 is designed to enable personnel to operate efficiently during an incident or event within the Incident Command System (ICS). ICS-200 provides training on and resources for personnel who are likely to assume a supervisory position within the ICS. IS-100 is a pre-requisite to the IS-200 course.

IS-800 National Response Plan (NRP)

The National Response Plan, or NRP, specifies how the resources of the Federal Government will work in concert with State, local, and tribal governments and the private sector to respond to Incidents of National Significance. This course introduces you to the NRP, including the concept of operations upon which the plan is built, roles and responsibilities of the key players, and the organizational structures used to manage these resources. The NRP provides a framework to ensure that we can all work together when our Nation is threatened.

ICS-300 Intermediate ICS for Expanding Incidents

ICS-300 and ICS-400 courses are courses conducted in a classroom. Both the Emergency Management Institute and the National Fire Academy sponsor NIMS compliant ICS-300 and 400 training. Please contact your local or State's Emergency Management Agency or State Fire Academy for details about when and where these courses will be available. (http://kyem.ky.gov/training/)

ICS-400 Advanced Incident Management System

ICS-300 and ICS-400 courses are courses conducted in a classroom. Both the Emergency Management Institute and the National Fire Academy sponsor NIMS compliant ICS-300 and 400 training. Please contact your local or State's Emergency Management.

2009 H1N1 INFLUENZA VACCINE

LIVE, ATTENUATED (the nasal spray vaccine)

WHAT YOU NEED TO KNOW

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.

1 What is 2009 H1N1 influenza?

2009 H1N1 influenza (sometimes called Swine Flu) is caused by a new strain of influenza virus. It has spread to many countries.

Like other flu viruses, 2009 H1N1 spreads from person to person through coughing, sneezing, and sometimes through touching objects contaminated with the virus.

Signs of 2009 H1N1 can include:
• Fatigue • Fever • Sore Throat • Muscle Aches
• Chills • Coughing • Sneezing

Some people also have diarrhea and vomiting.

Most people feel better within a week. But some people get pneumonia or other serious illnesses. Some people have to be hospitalized and some die.

2 How is 2009 H1N1 different from regular (seasonal) flu?

Seasonal flu viruses change from year to year, but they are closely related to each other.

People who have had flu infections in the past usually have some immunity to seasonal flu viruses (their bodies have built up some ability to fight off the viruses).

The 2009 H1N1 flu virus is a new virus strain. It is very different from seasonal flu viruses.

Most people have little or no immunity to 2009 H1N1 flu (their bodies are not prepared to fight off the virus).

3 2009 H1N1 influenza vaccine

Vaccines are available to protect against 2009 H1N1 influenza.

- These vaccines are made just like seasonal flu vaccines.
- They are expected to be as safe and effective as seasonal flu vaccines.
- They will not prevent "influenza-like" illnesses caused by other viruses.
- They will not prevent seasonal flu. ***You should also get seasonal influenza vaccine, if you want protection from seasonal flu.***

Live, attenuated intranasal vaccine (or **LAIV**) is sprayed into the nose. **This sheet describes the live, attenuated intranasal vaccine.**

An **inactivated** vaccine is also available, which is given as a shot. It is described in a separate sheet.

The 2009 H1N1 LAIV does not contain thimerosal or other preservatives. It is licensed for people from 2 through 49 years of age.

The vaccine virus is attenuated (weakened) so it will not cause illness.

4 Who should get 2009 H1N1 influenza vaccine and when?

WHO

LAIV is approved for people from 2 through 49 years of age who are not pregnant and do not have certain health conditions (see number 5 below). Groups recommended to receive 2009 H1N1 LAIV first are healthy people who:

- are from 2 through 24 years of age,
- are from 25 through 49 years of age and
  - live with or care for infants younger than 6 months of age, or
  - are health care or emergency medical personnel.

As more vaccine becomes available, other healthy 25 through 49 year olds should also be vaccinated.

> Note: While certain groups should not get LAIV – for example pregnant women, people with long-term health problems, and children from 6 months to 2 years of age – it is important that they be vaccinated . They should get the flu shot.

The Federal government is providing this vaccine for receipt on a voluntary basis. However, state law or employers may require vaccination for certain persons.

WHEN

Get vaccinated as soon as the vaccine is available.

Children through 9 years of age should get **two doses** of vaccine, about a month apart. Older children and adults need only one dose.

5 Some people should not get the vaccine or should wait

You should not get 2009 H1N1 LAIV if you have a **severe (life-threatening) allergy** to **eggs**, or to **any other substance in the vaccine**. *Tell the person giving you the vaccine if you have any severe allergies.*

2009 H1N1 LAIV should not be given to the following groups.

- children younger than 2 and adults 50 years and older
- pregnant women,
- anyone with a weakened immune system,
- anyone with a long-term health problem such as
  - heart disease
  - kidney or liver disease
  - lung disease
  - metabolic disease such as diabetes
  - asthma
  - anemia and other blood disorders
- children younger than 5 years with asthma or one or more episodes of wheezing during the past year,
- anyone with certain muscle or nerve disorders (such as cerebral palsy) that can lead to breathing or swallowing problems,
- anyone in close contact with a person with a *severely* weakened immune system (requiring care in a protected environment, such as a bone marrow transplant unit),
- children or adolescents on long-term aspirin treatment.

If you are moderately or severely ill, you might be advised to wait until you recover before getting the vaccine. If you have a mild cold or other illness, there is usually no need to wait.

Tell your doctor if you ever had:

- a life-threatening allergic reaction after a dose of seasonal flu vaccine,
- Guillain-Barré syndrome (a severe paralytic illness also called GBS).

These may not be reasons to avoid the vaccine, but the medical staff can help you decide.

2009 H1N1 LAIV may be given at the same time as most other vaccines. Tell your doctor if you got any other vaccines within the past month or plan to get any within the next month. H1N1 LAIV and seasonal LAIV should not be given together.

6 What are the risks from 2009 H1N1 LAIV?

A vaccine, like any medicine, could cause a serious problem, such as a severe allergic reaction. But the risk of any vaccine causing serious harm, or death, is extremely small.

The risks from 2009 H1N1 LAIV are expected to be similar to those from seasonal LAIV:

Mild problems:

Some children and adolescents 2-17 years of age have reported mild reactions, including:

- runny nose, nasal congestion or cough
- fever
- headache and muscle aches
- wheezing
- abdominal pain or occasional vomiting or diarrhea

Some adults 18-49 years of age have reported:

- runny nose or nasal congestion
- sore throat
- cough, chills, tiredness/weakness
- headache

Severe problems:

- Life-threatening allergic reactions to vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the vaccination.
- In 1976, an earlier type of inactivated swine flu vaccine was associated with cases of Guillain-Barré Syndrome (GBS). LAIV has not been linked to GBS.

7 What if there is a severe reaction?

What should I look for?

Any unusual condition, such as a high fever or behavior changes. Signs of a severe allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** the doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

8 Vaccine injury compensation

If you or your child has a reaction to the vaccine, your ability to sue is limited by law.

However, a federal program has been created to help pay for the medical care and other specific expenses of certain persons who have a serious reaction to this vaccine. For more information about this program, call **1-888-275-4772** or visit the program's website at:
www.hrsa.gov/countermeasurescomp/default.htm.

9 How can I learn more?

- Ask your provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's website at **www.cdc.gov/h1n1flu** or **www.cdc.gov/flu**
  - Visit the web at **www.flu.gov**

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

Vaccine Information Statement
2009 H1N1 LAIV 10/2/09

2009 H1N1 INFLUENZA VACCINE

INACTIVATED (the "flu shot")

WHAT YOU NEED TO KNOW

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.

1 What is 2009 H1N1 influenza?

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Like other flu viruses, 2009 H1N1 spreads from person to person through coughing, sneezing, and sometimes through touching objects contaminated with the virus.

Signs of 2009 H1N1 can include:

• Fatigue • Fever • Sore Throat • Muscle Aches
• Chills • Coughing • Sneezing

Some people also have diarrhea and vomiting.

Most people feel better within a week. But some people get pneumonia or other serious illnesses. Some people have to be hospitalized and some die.

2 How is 2009 H1N1 different from regular (seasonal) flu?

Seasonal flu viruses change from year to year, but they are closely related to each other.

People who have had flu infections in the past usually have some immunity to seasonal flu viruses (their bodies have built up some ability to fight off the viruses).

The 2009 H1N1 flu is a new flu virus. It is very different from seasonal flu viruses.

Most people have little or no immunity to 2009 H1N1 flu (their bodies are not prepared to fight off the virus).

3 2009 H1N1 influenza vaccine

Vaccines are available to protect against 2009 H1N1 influenza.

- These vaccines are made just like seasonal flu vaccines.
- They are expected to be as safe and effective as seasonal flu vaccines.
- They will not prevent "influenza-like" illnesses caused by other viruses.
- They will not prevent seasonal flu. ***You should also get seasonal influenza vaccine, if you want to be protected against seasonal flu***.

Inactivated vaccine (vaccine that has killed virus in it) is injected into the muscle, like the annual flu shot. **This sheet describes the inactivated vaccine.**

A **live, intranasal** vaccine (the nasal spray vaccine) is also available. It is described in a separate sheet.

Some inactivated 2009 H1N1 vaccine contains a preservative called thimerosal to keep it free from germs. Some people have suggested that thimerosal might be related to autism. In 2004 a group of experts at the Institute of Medicine reviewed many studies looking into this theory, and found no association between thimerosal and autism. Additional studies since then reached the same conclusion.

4 Who should get 2009 H1N1 influenza vaccine and when?

WHO

Groups recommended to receive 2009 H1N1 vaccine first are:

- Pregnant women
- People who live with or care for infants younger than 6 months of age
- Health care and emergency medical personnel
- Anyone from 6 months through 24 years of age
- Anyone from 25 through 64 years of age with certain chronic medical conditions or a weakened immune system

As more vaccine becomes available, these groups should also be vaccinated:

- Healthy 25 through 64 year olds
- Adults 65 years and older

The Federal government is providing this vaccine for receipt on a voluntary basis. However, state law or employers may require vaccination for certain persons.

WHEN

Get vaccinated as soon as the vaccine is available.

Children through 9 years of age should get **two doses** of vaccine, about a month apart. Older children and adults need only one dose.

5 Some people should not get the vaccine or should wait

You should not get 2009 H1N1 flu vaccine if you have a **severe (life-threatening) allergy** to **eggs**, or to **any other substance in the vaccine**. *Tell the person giving you the vaccine if you have any severe allergies*.

Also tell them if you have ever had:
- a life-threatening allergic reaction after a dose of seasonal flu vaccine,
- Guillain Barré Syndrome (a severe paralytic illness also called GBS).

These may not be reasons to avoid the vaccine, but the medical staff can help you decide.

If you are moderately or severely ill, you might be advised to wait until you recover before getting the vaccine. If you have a mild cold or other illness, there is usually no need to wait.

Pregnant or breastfeeding women can get inactivated 2009 H1N1 flu vaccine.

Inactivated 2009 H1N1 vaccine may be given at the same time as other vaccines, including seasonal influenza vaccine.

6 What are the risks from 2009 H1N1 influenza vaccine?

A vaccine, like any medicine, could cause a serious problem, such as a severe allergic reaction. But the risk of any vaccine causing serious harm, or death, is extremely small.

The virus in inactivated 2009 H1N1 vaccine has been killed, so you cannot get influenza from the vaccine.

The risks from inactivated 2009 H1N1 vaccine are similar to those from seasonal inactivated flu vaccine:

Mild problems:

- soreness, redness, tenderness, or swelling where the shot was given • fainting (mainly adolescents)
- headache, muscle aches • fever • nausea

If these problems occur, they usually begin soon after the shot and last 1-2 days.

Severe problems:

- Life-threatening allergic reactions to vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the shot.
- In 1976, an earlier type of swine flu vaccine was associated with cases of Guillain-Barré Syndrome (GBS). Since then, flu vaccines have not been clearly linked to GBS.

7 What if there is a severe reaction?

What should I look for?

Any unusual condition, such as a high fever or behavior changes. Signs of a severe allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** the doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

8 Vaccine injury compensation

If you or your child has a reaction to the vaccine, your ability to sue is limited by law.

However, a federal program has been created to help pay for the medical care and other specific expenses of certain persons who have a serious reaction to this vaccine. For more information about this program, call **1-888-275-4772** or visit the program's website at: **www.hrsa.gov/countermeasurescomp/default.htm**.

9 How can I learn more?

- Ask your provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's website at **www.cdc.gov/h1n1flu** or **www.cdc.gov/flu**
- Visit the web at **www.flu.gov**

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

The Flu and You
What to Know about the Flu Vaccine

One of the best ways to protect against the flu is to get a flu vaccine each year. Below are lists of who should get the seasonal flu vaccine and the H1N1 (swine flu) vaccine. There are two types of vaccine — the flu shot and flu nose spray.

Seasonal Flu

Seasonal flu is the term used for the yearly flu viruses that occur, usually during late fall and winter.

Who needs a seasonal flu vaccine?
Anyone who wants to reduce their chances of getting the flu can get a vaccine. The vaccine is recommended for:

- Children age 6 months to 19 years old.
- Pregnant women.
- People 50 years old or older.
- People of any age with chronic health problems.
- People who live in nursing homes and other long-term care facilities.
- Health care workers.
- Caregivers of or people who live with a person at high risk for complications from the flu.
- Out-of-home caregivers of or people who live with children less than 6 months old.

When should I get the seasonal flu vaccine?
The seasonal flu vaccine is already available in many places. The best time to get the vaccine is September through December.

Prevent the spread of flu:
- Wash your hands often in warm, soapy water.
- Cover your cough or sneeze.
- If you have a fever, stay home. Do not return to work or school until your fever has been gone 24 hours.

For more information:
- Flu information — flu.gov
- Kentucky flu information — healthalerts.ky.gov
- Centers for Disease Control and Prevention information hot line — 1-800-CDC-INFO

2009 H1N1 (Swine Flu)

2009 H1N1 (swine flu) is a new strain of flu that began infecting people in spring 2009 and has since spread worldwide. Swine flu is spread the same way seasonal flu viruses are spread.

Who needs a swine flu vaccine?
These groups are recommended to get the swine flu vaccine before others because they may be at risk for developing severe health problems if they become ill with swine flu:
- Pregnant women.
- People who live with or care for children younger than 6 months old.
- Health care and emergency medical services workers.
- Children and young adults 6 months through 24 years old, especially those with chronic health problems.
- People 25-64 years old with chronic health conditions.

Depending on vaccine availability, there may be further prioritization of these groups.

If you are not in one of these groups:
All other people age 25 to 64 years old should get the vaccine after the above groups have received it.

If you are 65 or older:
The risk for infection among people 65 or older appears to be less than the risk for younger age groups. People in this age group should be first in line to get the seasonal flu vaccine. They should wait until other groups have been vaccinated to get the swine flu vaccine, when there is plenty available.

When should I get the swine flu vaccine?
If you are in a high risk group, you should get it when it is made available. Health officials expect the vaccine will be made available in mid-October.

FREQUENTLY ASKED QUESTIONS ABOUT H1N1 (SWINE FLU)

WHAT IS H1N1 INFLUENZA (SWINE FLU) AND HOW DOES IT SPREAD?

There are many types of influenza or "flu."

- A new strain of influenza A (H1N1) began spreading worldwide among people in spring 2009.
- This flu virus is sometimes called "swine flu."
- H1N1 (swine flu) spreads the same way the seasonal flu virus does, through droplets from the coughing or sneezing of infected people. It also spreads by touching objects a sick person touched and then touching the nose or mouth.

FOR MORE INFORMATION:

KY Cabinet for Health and Family Services Frankfort, KY
FOR MEDIA: 1-502-564-6786
http://chfs.ky.gov
http://healthalerts.ky.gov

KY Regional Poison Center Louisville, KY
EMERGENCY: 1-800-222-1222
http://www.krpc.com/

The Centers for Disease Control and Prevention (CDC) Atlanta, GA
Toll free: 1-800-232-4636
http://www.cdc.gov/h1n1flu

WHEN DID H1N1 (SWINE FLU) BECOME A PANDEMIC?

- A flu pandemic is caused by a new flu virus that people have not been exposed to before. The flu virus spreads quickly from person to person.
- The first human cases of this outbreak in the U.S. occurred in late March and early April 2009. Kentucky's first case was reported in late April. The World Health Organization declared 2009 H1N1 (swine flu) a pandemic in June 2009.

WHAT ARE THE SIGNS AND SYMPTOMS OF H1N1 (SWINE FLU)?

- Fever higher than 100 degrees Fahrenheit
- Chills
- Cough
- Headache
- Sore throat
- Stuffy nose
- Muscle aches
- Diarrhea and vomiting have been reported by some people

WHAT CAN PEOPLE DO TO PREVENT SWINE FLU?

The same steps you take to prevent the common cold and seasonal flu apply when trying to prevent H1N1 (swine flu). The following are some general steps a family can take:

- Wash hands often with soap and water or use waterless, alcohol-based hand rubs.
- Cover the nose and mouth with a handkerchief or tissue when sneezing or coughing.
- Avoid touching the eyes, mouth, and nose, when coughing or sneezing.
- Keep children home from school, day care or other social gatherings if they are sick.
- Stay home from work or other public settings if you are sick.
- Avoid crowded places where people are confined in an indoor space.

IF PEOPLE ARE SICK WITH H1N1 (SWINE FLU), WHAT SHOULD THEY DO?

Since the severity of H1N1 is similar to seasonal flu, people who are sick with H1N1 (swine flu) should do the same things they would do if sick with seasonal flu:

- If you are sick, you should stay home and avoid contact with other people as much as possible to keep from spreading your illness to others.
- If you have a fever, difficulty breathing, a cough, body aches, runny nose, sore throat, nausea, vomiting or diarrhea, you should talk with a health care provider by telephone.
- Your health care provider will determine whether testing or treatment is needed.
- Before visiting a health care setting, tell the provider about your symptoms.
- Do not travel or go to work or school while sick, and limit your contact with others as much as possible to help prevent the spread of illness.

WHEN SHOULD I SEEK PROFESSIONAL TREATMENT?

If you become ill and experience any of the following warning signs, seek emergency medical care:

- Difficulty breathing or shortness of breath
- Pain or pressure in the chest or abdomen
- Sudden dizziness
- Confusion
- Severe or persistent vomiting

PREGUNTAS FRECUENTES SOBRE H1N1 (GRIPE PORCINA)

¿QUÉ ES LA INFLUENZA H1N1 (GRIPE PORCINA) Y CÓMO SE PROPAGA?

Existen muchos tipos de influenza o "gripe."

- Una nueva cepa de influenza A (H1N1) empezó a propagarse entre las personas por todo el mundo en la primavera de 2009.
- Este virus de la influenza a veces es llamado "gripe porcina".
- H1N1 (gripe porcina) se propaga de la misma manera que el virus de la influenza estacional, a través de gotitas cuando personas infectadas tosen o estornudan. También se propaga cuando uno toca objetos que una persona enferma tocó y luego se toca la nariz o la boca.

PARA MÁS INFORMACIÓN:

KY Cabinet for Health and Family Services Frankfort, KY
PARA LA PRENSA: 1-502-564-6786
http://chfs.ky.gov
http://healthalerts.ky.gov

KY Regional Poison Center (control de venenos) Louisville, KY
EMERGENCIAS: 1-800-222-1222
http://www.krpc.com/

The Centers for Disease Control and Prevention (CDC) Atlanta, GA
Sin cargo: 1-800-232-4636
http://www.cdc.gov/h1n1flu

¿CUÁNDO SE CONVIRTIÓ EN PANDEMIA LA INFLUENZA H1N1 (GRIPE PORCINA)?

- Una pandemia de influenza es causada por un nuevo virus de la influenza a que las personas no han sido expuestas antes. El virus de la influenza se propaga rápidamente de una persona a otra.
- Los primeros casos humanos de este brote en los EE. UU. ocurrieron a finales de marzo y principios de abril de 2009. El primer caso en Kentucky fue reportado a finales de abril. La Organización Mundial de la Salud declaró la influenza H1N1 de 2009 (gripe porcina) una pandemia en junio de 2009.

¿CUÁLES SON LOS SIGNOS Y SÍNTOMAS DE LA INFLUENZA H1N1 (GRIPE PORCINA)?

- Fiebre mayor de 100 grados Fahrenheit (38 grados centígrados)
- Escalofríos
- Tos
- Dolor de cabeza
- Dolor de garganta
- Nariz congestionada
- Dolores musculares
- Algunas personas han informado que causa diarrea y vómitos

¿QUÉ SE PUEDE HACER PARA PREVENIR LA GRIPE PORCINA?

Los mismos pasos que usted toma para prevenir el resfriado común y la influenza estacional aplican cuando intenta prevenir la influenza H1N1 (gripe porcina). Los siguientes son unos pasos generales que una familia puede tomar:

- Lavarse las manos frecuentemente con jabón y agua o usar geles sin agua con base de alcohol para las manos.
- Cubrirse la nariz y la boca con un pañuelo o un pañuelo desechable cuando estornuda o tose.
- Evitar tocarse los ojos, la boca y la nariz cuando tose o estornuda.
- No permitir que los niños vayan a la escuela, a la guardería ni a otras reuniones sociales si están enfermos.
- Quedarse en casa y no ir al trabajo ni a otros entornos públicos si usted está enfermo.
- Evitar lugares con muchedumbre donde las personas están restringidas en un espacio interior.

SI UNO ESTÁ ENFERMO CON H1N1 (GRIPE PORCINA), ¿QUÉ DEBE HACER?

Puesto que la severidad de H1N1 es parecida a la de la influenza estacional, las personas que están enfermas con H1N1 (gripe porcina) deben hacer las mismas cosas que harían si estuvieran enfermas con la influenza estacional:

- Si usted está enfermo, debe quedarse en casa y evitar el contacto con otras personas lo más que pueda para prevenir la propagación de la enfermedad a otras personas.
- Si tiene fiebre, dificultades respiratorias, tos, dolores del cuerpo, mocos, dolor de garganta, náuseas, vómitos o diarrea, debe hablar con un proveedor de atención médica por teléfono.
- Su proveedor de atención médica determinará si necesita pruebas o tratamientos.
- Antes de visitar un centro de atención médica, dígale al proveedor cuáles son sus síntomas.
- No viaje ni vaya al trabajo ni a la escuela mientras esté enfermo, y limite su contacto con otras personas lo más que pueda para ayudar a prevenir la propagación de la enfermedad.

¿CUÁNDO DEBO BUSCAR TRATAMIENTO DE UN PROFESIONAL?

Si usted se enferma y tiene alguna de las siguientes señales de aviso, busque atención médica de emergencia:

- Dificultades respiratorias o falta de aliento
- Dolor o presión en el pecho o en el abdomen
- Mareos repentinos
- Confusión
- Vómitos graves o continuos

FACT SHEET – *Swine Flu (H1N1)*

Swine Flu (H1N1) is a new type of flu.

Swine flu (H1N1) is a new strain of flu that is spread the same way seasonal flu viruses are, but it is different. People can spread the flu virus when they cough or sneeze. You can get swine flu by touching something with the flu virus on it. You will need to get separate flu shots for seasonal flu and swine flu.

You can get swine flu from other people.

To protect yourself and others from swine flu:

- Wash your hands often with soap and warm water.
- Cough into your sleeve, not your hand.
- Keep away from people who are sick with the flu.

To care for someone with the swine flu:

- Check for a fever.
- Give the person small amounts of water (if not throwing up).
- Put used tissues in a trash bag.
- Keep the person at home for at least 24 hours after the fever is gone.

FOR MORE INFORMATION:

Kentucky Cabinet for Health and Family Services Frankfort, Ky.
http://healthalerts.ky.gov

Kentucky Regional Poison Center Louisville, Ky.
EMERGENCY: 1-800-222-1222
http://www.krpc.com

[INSERT Local Health Dept Name]
[INSERT Local Health Dept phone #]

The Centers for Disease Control and Prevention (CDC) Atlanta, Ga.
Toll free: 1-800-232-4636
http://www.cdc.gov/h1n1flu

Swine flu can make you feel very sick. Contact your doctor or health care provider if you have:

- Fever higher than 100 degrees
- Headache
- Cough
- Weak and tired
- Diarrhea
- Chills
- Sore throat
- Stuffy nose
- Throwing up

Contact your doctor or health care provider right away if you or your child:

- Has trouble breathing
- Feels pain in the chest or stomach area
- Is not waking up
- Feels dizzy
- Throws up often

HOJA INFORMATIVA – *Influenza porcina (H1N1)*

La influenza porcina (H1N1) es un nuevo tipo de influenza, o gripe.

La influenza porcina (H1N1) es una nueva cepa de influenza, o gripe, que se propaga en la misma manera en que se propagan los virus de la influenza estacional, pero esta cepa es distinta. Las personas pueden propagar el virus de la influenza cuando tosen o estornudan. Usted puede contraer la influenza porcina al tocar algo que tiene el virus de la influenza. Necesitará recibir vacunas distintas contra la influenza estacional y la influenza porcina.

Puede contagiarse de la influenza porcina por otras personas.

Para protegerse y proteger a otros de la influenza porcina:

- Lávese las manos frecuentemente con jabón y agua tibia.
- Tosa en la manga y no en la mano.
- Manténgase alejado de personas que están enfermos con la influenza.

Para cuidar a alguien que tiene la influenza porcina:

- Vea si tiene fiebre.
- Déle pequeñas cantidades de agua a la persona (si no tiene vómitos).
- Ponga los pañuelos desechables en una bolsa de basura.
- Haga que la persona se quede en casa por lo menos 24 horas después de que ya no haya fiebre.

PARA MÁS INFORMACIÓN:

Kentucky Cabinet for Health and Family Services Frankfort, Ky.
http://healthalerts.ky.gov

Kentucky Regional Poison Center (control de venenos) Louisville, Ky.
EMERGENCIAS: 1-800-222-1222
http://www.krpc.com

[INSERT Local Health Dept Name]
[INSERT Local Health Dept phone #]

The Centers for Disease Control and Prevention (CDC) Atlanta, Ga.
Sin cargo: 1-800-232-4636
http://www.cdc.gov/h1n1flu

La influenza porcina puede causar que usted se sienta muy enfermo. Comuníquese con su doctor o proveedor de atención médica si usted tiene:

- Fiebre mayor de 100.4° F (38° C)
- Dolor de cabeza
- Tos
- Debilidad y cansancio
- Diarrea
- Escalofríos
- Dolor de garganta
- Nariz congestionada
- Vómitos

Comuníquese con su doctor o proveedor de atención médica de inmediato si usted o su niño:

- Tiene dificultades en respirar
- Siente dolor en el área del pecho o estómago
- No se despierta
- Tiene mareos
- Vomita muchas veces

Stop the Spread of Flu

The flu is a virus that affects the body's respiratory system. It can be easily passed from person to person. Symptoms of flu include: fever, headache, extreme tiredness, dry cough, sore throat, runny or stuffy nose and muscle aches.

This year, a strain of flu called novel H1N1 (swine flu) began infecting people and has since spread worldwide. Swine flu is not the same as seasonal flu that occurs yearly. But it spreads the same way the seasonal flu virus spreads. Flu spreads when sick people cough or sneeze. It also spreads by touching objects a sick person touched and then touching your nose or mouth.

Depending on your age and health status, you may need both a seasonal flu shot now and a swine flu shot later, when it is made available.

What you can do to prevent flu:

Prevent the spread of flu with common sense and good hygiene. Follow these tips to avoid flu:

- Wash your hands in warm, soapy water for 15 to 20 seconds — about the time it takes to sing "Happy Birthday" twice.
- Teach children good health habits.
- Cover your cough or sneeze.
- Stay at home if you are sick and contact your health care provider.
- Get a flu shot — you may need a seasonal flu shot and an H1N1 (swine flu) shot.
- Stay informed.

For more information about flu:

Online: healthalerts.ky.gov or flu.gov.

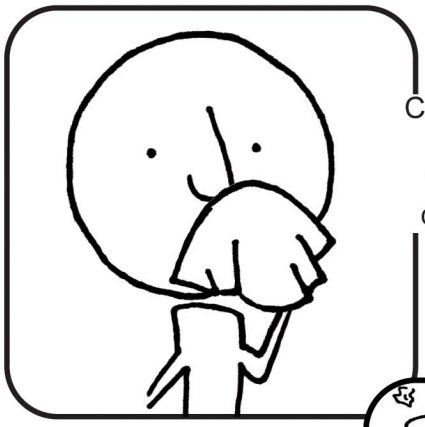
Phone: 1-800-CDC-INFO (800-232-4636)

Kentucky UNBRIDLED SPIRIT™

Kentucky Department for Public Health

Stop the spread of germs that make you and others sick!

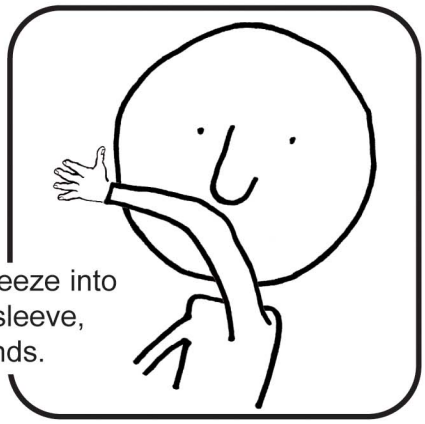
Cover your Cough



Cover your mouth and nose with a tissue when you cough or sneeze

or

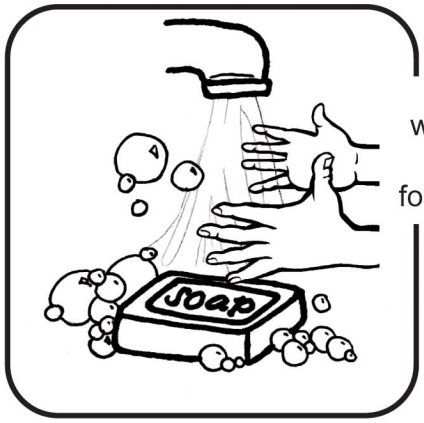
cough or sneeze into your upper sleeve, not your hands.



Put your used tissue in the waste basket.

Clean your Hands

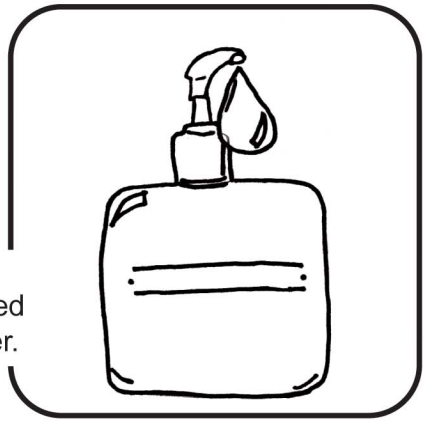
after coughing or sneezing.



Wash hands with soap and warm water for 20 seconds

or

clean with alcohol-based hand cleaner.



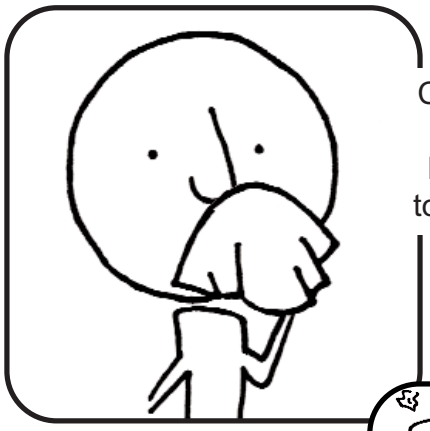
Minnesota Department of Health
717 SE Delaware Street
Minneapolis, MN 55414
612-676-5414 or 1-877-676-5414
www.health.state.mn.us

Minnesota Antibiotic Resistance Collaborative

ASSOCIATION FOR PROFESSIONALS IN INFECTION CONTROL AND EPIDEMIOLOGY, INC.

¡Pare la propagación de gérmenes que lo enferman a usted y a otras personas!

Cubra su tos



Cubra su boca y nariz con un kleenex cuando tosa o estornude

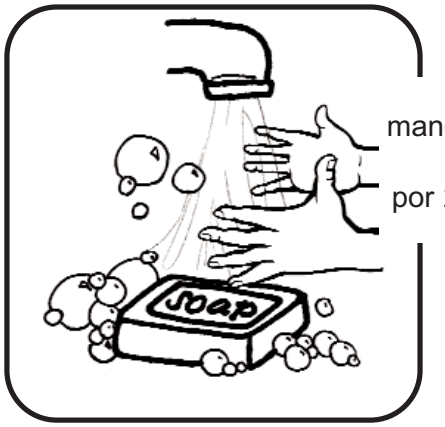
or

tosa o estornude en la manga de su camisa, no en sus manos.

Deseche el kleenex sucio en un basurero.

Lávese las manos

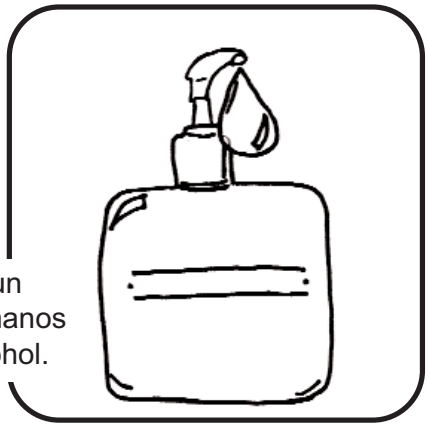
después de toser o estornudar.



Lávese las manos con jabón y agua tibia por 20 segundos

o

límpielas con un limpiador de manos a base de alcohol.



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Minnesota Antibiotic Resistance Collaborative

¡Pare la propagación de gérmenes que lo enferman a usted y a otras personas!

Cubra su tos

Cubra su boca y nariz con un kleenex cuando tosa o estornude

o

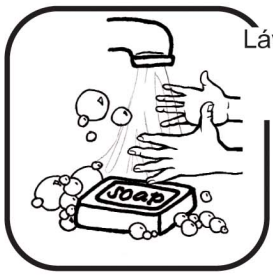
tosa o estornude en la manga de su camisa, no en sus manos.

Deseche el kleenex sucio en un basurero.

Quizás le pidan ponerse una mascarilla quirúrgica para proteger a otras personas.

Lávese las manos

después de toser o estornudar.



Lávese las manos con jabón y agua tibia por 20 segundos

o

límpielas con un limpiador de manos a base de alcohol.

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717 SE Delaware Street
Minneapolis, MN 55414
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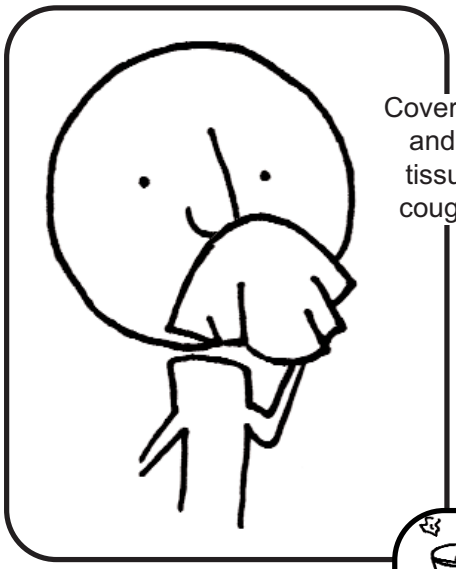
Minnesota Antibiotic Resistance Collaborative

Stop the spread of germs that make you and others sick!

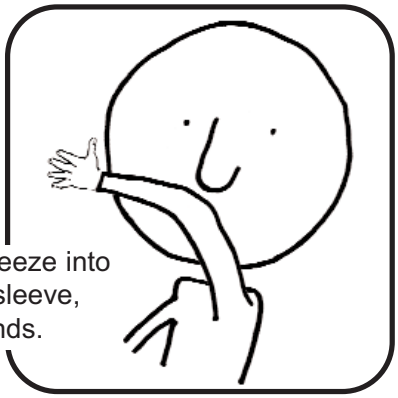
Cover your Cough



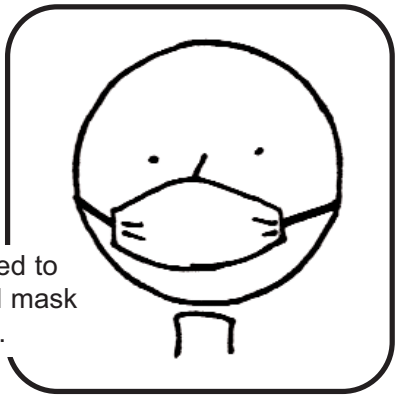
Cover your mouth and nose with a tissue when you cough or sneeze

or

cough or sneeze into your upper sleeve, not your hands.



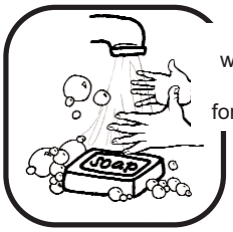
Put your used tissue in the waste basket.



You may be asked to put on a surgical mask to protect others.

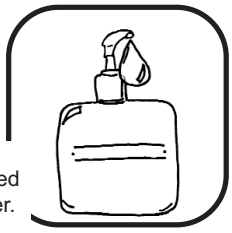
Clean your Hands

after coughing or sneezing.



Wash hands with soap and warm water for 20 seconds *or*

clean with alcohol-based hand cleaner.



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Minnesota Antibiotic Resistance Collaborative

Swine flu nasal vaccine: Is it right for you?

The H1N1 flu (swine flu) vaccine is currently available in limited amounts in the form of a nasal (nose) spray. People in these target groups should be the **first** to take the nose spray vaccine to lessen their risk of swine flu:

■ Healthy people 2 to 24 years old.
■ Healthy people 2 to 49 years old who live with or care for children younger than 6 months old.
■ Healthy health care or emergency medical services workers who are 49 years old or younger.

People who should **only receive shots** because the nose spray is not recommended for them:

■ Pregnant women.
■ Any person with a chronic health problem.
■ People 50 and older.

Swine flu shots should be ready in late October for people who cannot take the nose spray. Ask your health care provider if he or she will be giving the swine flu vaccine. Talk with your health care provider or local health department about which flu vaccine is best for you and when you should get it.

Kentucky
UNBRIDLED SPIRIT™

What you can do to prevent flu:

Prevent the spread of flu with common sense and good hygiene. Follow these tips to avoid flu:

■ Wash your hands in warm, soapy water for 15 to 20 seconds — about the time it takes to sing “Happy Birthday” twice.

■ If you cannot wash your hands, use an alcohol-based hand gel.

■ Teach children good health habits.

■ Cover your cough or sneeze with a tissue. If you do not have a tissue, cough into the crook of your elbow, not your hand.

■ Stay at home if you are sick and contact your health care provider.

■ Get a swine flu vaccine (nose spray or shot) — you may need a seasonal flu vaccine and a swine flu vaccine.

For more information:
■ Flu information — flu.gov
■ Kentucky flu information — healthalerts.ky.gov
■ Centers for Disease Control and Prevention information hot line — 1-800-CDC-INFO

Kentucky Department for Public Health/09-09

Flu vaccines for people age 50 and older

You could be exposed to two kinds of flu this flu season. There is a vaccine for each type, one for seasonal flu and one for H1N1 (swine flu). The Kentucky Department for Public Health wants you to know how to reduce your risk of getting the flu. Follow these steps to make sure you are protected:

Should people 50 and older get the seasonal flu vaccine?
If you are 50 or older, you fall into the group of people who should receive the **seasonal flu vaccine,** which is available now. Seasonal flu is the term used for yearly flu viruses that occur usually during late fall and winter.

What groups of people age 50 to 64 should get the swine flu vaccine first?
People who are age 50 to 64 in these target groups should get the vaccine when it is first made available:

- People with chronic health conditions.
- Household contacts or caregivers of children younger than 6 months old.
- Health care and emergency medical services workers.

All other people age 50 to 64 should get the swine flu vaccine after the target groups have received it.

People age 65 or older are not in a target group for receiving swine flu vaccine first because they appear to be less at risk for swine flu than younger people. Health experts say people in this age group may have some immunity to the swine flu. However, some people 65 and older will become sick with swine flu and could have complications. Any person in this age group who has flu-like symptoms should contact a health care provider immediately. People in this age group should get the swine flu vaccine after target groups have received it.

The Centers for Disease Control and Prevention **does not expect** there will be a shortage of swine flu vaccine, but vaccine availability and demand can be unpredictable. The vaccine will be ready in mid- to late-October. It is likely that the vaccine will be available in limited quantities in the beginning.

Should I get the vaccine as a flu shot or as the nasal mist?
People age 50 and older should only receive shots. They should not receive nasal mist vaccine for seasonal flu or swine flu. The nasal mist is not recommended for anyone older than 49.

Prevent the spread of flu:

- Wash your hands often in warm, soapy water.
- Avoid touching your eyes, nose or mouth.
- Cover your cough or sneeze.
- If you have a fever, stay home. Do not return to work until your fever has been gone 24 hours.

For more information:

- Flu information — flu.gov
- Kentucky flu information — healthalerts.ky.gov
- Centers for Disease Control and Prevention information hot line — 1-800-CDC-INFO

Kentucky Department for Public Health — 9/09

How To Care for Someone with Swine Flu

What are the signs and symptoms of the swine flu?

- Sudden onset of illness
- Fever higher than 100.4 degrees Fahrenheit
- Chills
- Cough
- Headache
- Sore throat
- Stuffy nose
- Muscle aches
- Feeling of weakness
- Diarrhea, vomiting, abdominal pain and/or exhaustion occur more commonly in children

FOR MORE INFORMATION:

KY Cabinet for Health and Family Services
Frankfort, KY
FOR MEDIA: 1-502-564-6786
http://chfs.ky.gov
http://healthalerts.ky.gov

KY Regional Poison Center
Louisville, KY
EMERGENCY: 1-800-222-1222
http://www.krpc.com/

The Centers for Disease Control and Prevention (CDC) Atlanta, GA
Toll free: 1-800-232-4636
http://www.cdc.gov/h1n1flu

How do you care for someone who has swine flu?

If you suspect that someone you live with has swine flu, the first thing to do is monitor their condition.

- Check the person's temperature using a digital thermometer.
- Check the person's skin for color (pink, pale or bluish) and rash.
- Monitor the amount of liquids a person consumes.
- Keep track of medications, dosages and times given.

Separate the person with swine flu from other people who live in the home.

- One person in the household should be the main caregiver for the sick person.
- People other than the caregiver who live in the home should limit contact with the sick person.
- The sick person should use a separate bathroom from other people in the house, if possible.

WHAT SHOULD BE PROVIDED TO THE SICK PERSON?

Several items should be made available to the sick person to make them as comfortable as possible.

- Use ibuprofen or acetaminophen for fever, sore throat and general discomfort. (Do not use aspirin in children or teenagers because it can cause Reye's syndrome, a life-threatening illness.)
- If the person is not vomiting, offer small amounts of liquids frequently to prevent dehydration, even if the person does not feel thirsty.
- Keep tissues and a trash bag for disposal within reach of the sick person.
- Do not allow the person to drink alcohol or use tobacco. Do not allow smoking in the house.

WHEN SHOULD I SEEK PROFESSIONAL TREATMENT?

If the person you are caring for experiences any of the following warning signs, seek emergency medical care:

- Difficulty breathing or shortness of breath
- Pain or pressure in the chest or abdomen
- Sudden dizziness
- Confusion
- Severe or persistent vomiting

HOW CAN YOU PREVENT THE SPREAD OF SWINE FLU IN THE HOME?

- Make sure all family members wash their hands often with soap and warm water or an alcohol-based hand sanitizer.
- All dishes and eating utensils should be washed in the dishwasher or by hand with warm water and soap. Separation of eating utensils for use by a patient is not necessary.
- Laundry can be washed in a standard washing machine or by hand with warm water and soap. It is not necessary to separate soiled linen from the patient from other household laundry.
- Tissues used by the sick person should be placed in a trash bag and thrown away.
- If you must have close contact with the sick person (for example, hold a sick infant), spend the least amount of time possible in close contact and try to wear a facemask (for example, surgical mask) or N95 disposable respirator. More information on facemasks and respirators can be found at www.cdc.gov/swineflu.

CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR PUBLIC HEALTH

Steven L. Beshear
Governor

Division of Administration & Financial Management
275 East Main Street, HS1W-C
Frankfort, Kentucky 40621
502-564-6663
502-564-0919 fax

Janie Miller
Secretary

MEMORANDUM

TO: **All Local Health Departments**

FROM: Rosie Miklavcic, RN BSN MPH
Chief Nursing Officer and Director of Administration & Financial Management

DATE: October 5, 2009

SUBJECT: Instructions for Reporting and Billing 2009 novel H1N1 Influenza Vaccinations

The Kentucky Department for Public Health (KDPH) encourages all local health departments to offer the novel H1N1 influenza vaccinations to targeted risk groups as soon as their vaccine becomes available. To avoid a missed opportunity, please offer H1N1 influenza vaccinations during all appropriate healthcare encounters.

Four (4) H1N1 influenza vaccine administration documents will be available from KDPH. These documents include the following:

- LHDO-2 SEASONAL Influenza and/or H1N1 Influenza, VACCINE ADMINISTRATION RECORD
- LHDO-3 H1N1 Influenza Vaccine ADMINISTRATION RECORD (NO Third Party Billing)
- LHDO-4 H1N1 Influenza Vaccine ADMINISTRATION RECORD (Third Party Billing)
- LHDO-5 SCHOOL FORM H1N1 Influenza Vaccine ADMINISTRATION RECORD

Please Note: The request for translation services of these forms has been submitted to the Cabinet for Health and Family Services. The Spanish versions will be forwarded to LHDs upon receipt.

The H1N1 Influenza Vaccine Administration forms and Vaccine Information Statements (VIS) for the live attenuated and the inactivated vaccine are included as attachments with this document.

BILLING INFORMATION

The H1N1 Influenza vaccine will be provided FREE by the Centers for Disease Control and Prevention. No provider will be allowed to charge patients for the H1N1 influenza vaccine.

In accordance with federal guidance, Kentucky local health departments (LHDs) **will not** be allowed to charge the patients directly for the administration of the H1N1 influenza vaccine as each LHD is a recipient of Public Health Emergency Response (PHER) funds. It is not permissible to charge patients in public health clinics or mass vaccination clinics conducted by or on behalf of a public health entity. A 'public health clinic' is defined as a clinic that is conducted by, or on behalf of a state or local health jurisdiction and receives PHER implementation funds to administer H1N1 vaccine in any setting. However private providers, whom you may have vaccine recipient agreements with and who do not receive PHER funds, may charge the patient for the administration of the H1N1 influenza vaccine.

It is permissible to bill third party payors/insurers in public health clinics or mass vaccination clinics conducted by, or on behalf of a public health entity. **LHDs are not allowed to charge the patient any co-payments or out-of-pocket charges.**

LHDs that choose to bill third party payors/insurers must report the administration through the Patient Services Reporting System (PSRS). LHDs that choose NOT to bill third party payors/insurers will NOT be required to report the administration through PSRS. However, any collection, reporting and billing of these administration services must meet the requirements of the third party payors/insurers.

The H1N1 vaccine administration may be reported/recorded on a Patient Encounter Form (PEF) with documentation in the patient medical record or on the attached vaccine administration records. In addition to the regular encounter entry screen, the Medicare Roster Billing Screen is available. The Roster Billing Process is acceptable for Medicare patients who receive their vaccine through a mass vaccination clinic.

BILLING OPTIONS

I. H1N1 influenza vaccine administration provided in the clinic, mass vaccinations sites, or school settings when Third Party Payors/Insurers will NOT be billed.

A. LHD will use the LHDO-3 form. You should collect the minimum demographics and obtain consent for administering the vaccine. Consent must be signed by the patient or parent/legal guardian after being provided the appropriate VIS form and had the opportunity to ask questions of the medical professional administering the vaccine. All of the data fields on the top half of the form are required. The health professional will complete the "*For Health Department Use ONLY*" area of the form.

B. Forms LHDO-2 (Seasonal and H1N1 Influenza combined form) and LHDO-5 (School setting form) may be used by placing an **"X"** through the insurance collection information section.

C. The LHDO abbreviated record forms will be used as the patient's medical record. The record must be kept for a minimum of three (3) years following vaccination.

II. H1N1 Influenza Vaccine administration provided in the clinic, mass vaccinations sites, or school settings when Third Party Payors/Insurers will be billed.

A. LHD will use the LHDO-4 form. This form includes the consent, assignment of benefits, and release of information for Medicare, Medicaid, and insurance billings. For those patients who are uninsured or underinsured you may **"X"** out the third party billing information on LHDO-4 or use the LHDO-3 form.

B. For H1N1 influenza vaccine administration provided in the clinic, you will have two reporting options for FY 2009-2010. You may use one of the H1N1 Influenza Vaccine Administration Records enclosed with this packet as an abbreviated record **or** when the H1N1 vaccine is administered in addition to a patient's other clinical services, you may continue to pull patient records and document the H1N1 influenza given as a regular clinic activity. *DPH recommends that since the H1N1 influenza vaccine is a **rarely offered vaccine** and the retention is not permanent, the H1N1 Influenza Administration Record be used in the clinic.*

C. Forms LHDO-2 (Seasonal and H1N1 Influenza combined form) and LHDO-5 (School form) may be used. If there is no third party billing, place an "X" through the insurance collection information section. If LHDO-2 is used and only the Seasonal Influenza will be charged/billed, then do not check the H1N1 influenza administration code in the "For Health Department Use Only" section.

D. For coding the H1N1 Influenza Vaccine Administration Record form, there is a space on the administration form for a label containing the system-assigned document number (PEF label). All data fields on the top half of the H1N1 Influenza Vaccine Administration Record form must be entered on the registration screen for the successful completion of the third-party billing process.

In addition, the form includes the consent, assignment of benefits, and release of information for Medicare, Medicaid, and other third party payors. The form must be signed by the patient after the patient has had the opportunity to ask questions of the medical professional administering the vaccine. The medical professional will complete the "For Health Department Use Only" area of the form.

The 80000 code will not be needed for entry on this service.

The G9142 H1N1 Influenza vaccine code does not need to be reported since it has been provided free from the CDC.

Only the G9141 administration code is required with the V0481 ICD code.

The recently released CPT codes 90470-H1N1 immunization administration (intramuscular or intranasal), including counseling when performed, and the 90663-

Influenza virus vaccine, pandemic formulation, H1N1, will be available in the PSRS for use with insurance companies that require these codes for billing purposes.

After the encounter is entered into the system, the abbreviated record is to be filed in a folder marked H1N1 Influenza 2009-2010 and retained for six years.

E. For coding on the PEF, if the sole purpose of the visit is for the H1N1 Influenza immunization, an Evaluation and Management (E/M) should NOT be reported. Payment **will not be made** to providers for office visits when the only purpose of the visit is the administration of either the seasonal and/or H1N1 vaccine(s).

If the H1N1 Influenza immunization is provided within the context of a visit for another purpose, simply report the H1N1 administration code (G9141 or 90470) in addition to all other CPTs which are appropriate to report for the visit.

III. Immunizations Provided in an Offsite Mass Vaccination Clinic

If influenza vaccinations are conducted in an offsite vaccination clinic, it is permissible to maintain an abbreviated record. The H1N1 influenza vaccine Administration Record is used as the medical record or the medical record/encounter form. There is a space on the form for the label which contains the system-assigned document number. If the label process is not feasible, you may obtain a block of numbers from the DPH Local Health Operations Help Desk and write in the document number. All of the data fields on the top half of the form are required. The form includes the consent, assignment of benefits, and release of information for Medicare, Medicaid, and other third party payors.

IV. Medicare policy regarding free flu services.

Governmental entities (such as Public Health Clinics) may bill Medicare for pneumococcal, Hepatitis B, and influenza virus vaccines administered to Medicare beneficiaries when services are rendered free of charge to non-Medicare beneficiaries. Information from the Claims Processing Manual 100-04, Chapter 18, Section 10.2.5.2. Link for more information: http://www.cms.hhs.gov/Manuals/IOM/list.asp

V. Time Coding and Billing

For LHDs choosing NOT to bill Third Party Payors/Insureres

- ALL disciplines involved in the administration of the H1N1 should report their time to the 731 Cost Center, regardless of the physical location where the service is delivered.

For LHDs choosing to bill Third Party Payors/Insurers

- Medical providers will report the amount of time spent administering H1N1 vaccine to those eligible patients to the 700 Cost Center.
- Clinical support staff will report all time spent for medical indirect for H1N1 activities to Cost Center 899 (this would include the collection of information for completing the H1N1 Influenza Administration form, reporting the information in the PSRS, and collecting payment from Third Party Payors/Insurers).

- For patients who do not have a Third Party Payor/Insurer, they would not be reported through the PSRS and time should be coded to the 731 Cost Center.
- Cost Center time coding will apply regardless of the physical location where the service is delivered. (i.e., the service is provided at a mass vaccination clinic or at your LHD, time coding depends on third-party billing).

LHDs may choose to utilize their Phase III (731) allocations before determining if there is a need to bill Third party Payors/Insurers.

VI. To Request Additional Providers

If the LHD will be billing third party payors/insurers, you must have a provider number for each volunteer or contracted nurse. If a LHD needs a provider number for an independent contractor and/or a personal service employee contract, please provide **the name, job title and who will be responsible for the third party billing**. These provider numbers are requested through the DPH Local Health Help Desk at the contact information below.

If you have any questions, please contact Local Health Operations Help Desk of the Division of Administration and Financial Management at (502) 564-6663, the Help Desk at CDM 2168, or e-mail LOCALHEALTH.HELPDESK@KY.GOV .

NOTE: The attached forms are inappropriate to use for other vaccinations other than the vaccine(s) it was designed for.

Local Health Departments
H1N1 Time Reporting and Billing

The Department for Public Health has revised the time reporting and billing guidance that was provided during the ITV conference on Wednesday, September 30, 2009.

For LHDs choosing NOT to bill Third Party Payors/Insurers:

- ALL disciplines involved in the administration of the H1N1 would report their time to the 731 Cost Center, regardless of the physical location where the service is delivered.

For LHDs choosing to bill Third Party Payors/Insurers:

- ***WITH A THIRD PARTY PAYOR SOURCE***: Medical Providers will report the amount of time spent administering H1N1 vaccine to those eligible patients to the 700 Cost Center
- Clinical Support Staff will report all time spent for medical indirect for H1N1 activities to Cost Center 899 (this would include the collection of information for completing the H1N1 Influenza Administration form, reporting the information in PSRS, and collecting payment from Third Party Payors/Insurers)
- ***WITHOUT A THIRD PARTY PAYOR SOURCE***: For patients who do not have a Third Party Payor/Insurer, they would not be reported through the PSRS and time should be coded to the 731 Cost Center.
- Cost Center time coding will apply regardless of the physical location where the service is delivered. (i.e., the service is provided at a mass clinic or at your LHD, time coding depends on Third Party Billing)

LHDs may choose to utilize their Phase III (731) allocations before determining if there is a need to bill Third Parties/Insurers.

If you have any questions, please contact Janet Overstreet at (502) 564-6663, ext. 3150 or e-mail JanetD.Overstreet@ky.gov

October 5, 2009

*LHD name*_____
*LHD address*_____
*Off-site Location*_____

PEF label OR

DOCUMENT#: _____

HID/LOC/SITE: _____

SEASONAL Influenza and/or H1N1 Influenza VACCINE ADMINISTRATION RECORD

NAME: _____ **SOCIAL SECURITY#:** _____

ADDRESS: _____
STREET CITY COUNTY STATE ZIP

BIRTHDATE: ____/____/____ **PHONE NUMBER:** _____
MONTH DAY YEAR

RACE: (Check ONE or MORE) ☐ **(W)** White ☐ **(B)** Black or African American ☐ **(N)** American Indian or Alaska Native

☐ **(A)** Asian ☐ **(H)** Native Hawaiian or Other Pacific Islander **ETHNICITY:** Hispanic or Latino **(Y)** Yes or **(N)** No

SEX: (Check ONE) ☐ Male ☐ Female **Vaccine For Children (**seasonal flu**) ELIGIBLE?** ☐ YES ☐ NO

DO YOU HAVE **MEDICAID** ? ☐ YES ☐ NO IF YES, **MEDICAID NUMBER**: _____

DO YOU HAVE **MEDICARE** ? ☐ YES ☐ NO IF YES, **MEDICARE NUMBER**: _____

DO YOU HAVE **HEALTH INSURANCE** ? ☐ YES ☐ NO

IF YES, **COMPANY NAME:** _____ **POLICY#:** _____

SUBSCRIBER'S NAME: **GROUP #:**

The health department may keep this record in a medical file. They will record what vaccine was given, when the vaccine was given, the name of the company that made the vaccine, the vaccine's special lot number, the vaccine injection site, the signature and title of the person who gave the vaccine, and the address where the vaccine was given.

"I have read or have had explained to me the 2009-2010 Vaccine Information Statement(s) (VIS) and understand the risks and benefits for the: (Check box(es))

- **( ) 2009-2010** *Inactivated* ***influenza vaccine, (VIS/EPID-239A Dated 08/11/09)***
- **( ) 2009-2010** *Live,* ***Intranasal influenza vaccine, (VIS/EPID-239B Dated 08/11/09)***
- **( ) 2009-2010** *Inactivated* ***H1N1 influenza vaccine, (VIS dated 10/2/09)***
- **( ) 2009-2010** *Live,* ***Intranasal H1N1 influenza vaccine, (VIS dated 10/2/09)***

☐ **ASSIGNMENT OF BENEFITS** I request that payment of authorized medical insurance benefits be made to the local health department listed above on behalf of above name, for services received. I also authorize the local health department to release medical information to Medicare, Other Third Payors (insurance carriers, Medicaid, etc.) and their agents to determine payment for services. I am aware that should Medicare refuse payment for the seasonal influenza vaccine service, I will be responsible for the cost. If I am covered by a billable private insurance, I am aware that I may be responsible for some additional charges not covered by my plan for the seasonal influenza vaccine. **I will not be responsible for any charges for the H1N1 vaccine or administration.**

X_____ **DATE:** _____

Signature of person to receive vaccine or person authorized to make the request (parent or legal guardian)

FOR HEALTH DEPARTMENT USE ONLY

(Seasonal Influenza Vaccine)

Vaccine Manufacturer:_____
Vaccine Lot Number:_____
Injection Site:_____
Signature and Title of Provider:_____
Provider:_____

(H1N1 Influenza Vaccine)

Vaccine Manufacturer:_____
Vaccine Lot Number:_____
Injection Site:_____
Signature and Title of Provider: _____
Provider# :_____

√	INFLUENZA (VFC)	√	INFLUENZA (NON-VFC)
	90655 Influenza:split-presrv free- ages 6-35 mths		90655NV Influenza:split-presrv free- ages 6-35 mths
	90656 Influenza:split-presrv free- ages 3-18 yrs		90656NV Influenza:split-presrv free- ages 3-18yrs
			90656 Influenza:split-presrv free- ages >18yrs
	90657 Influenza:split- ages 6-35 mths		90657NV Influenza:split- ages 6-35 mths
	90658 Influenza:split- ages 3-18 yrs		90658NV Influenza- ages 3-18 yrs
			90658 Influenza- ages >18 yrs
	90660 Influenza:Intranasal-ages 2-18 yrs		90660NV Influenza: Intranasal- ages 2-18 yrs
	(Use FR Modifier if NO Insurance or Under-insured)		90660 Influenza: Intranasal- ages 19-49 yrs

√	ADMINISTRATION of H1N1 or Seasonal INFLUENZA Vaccine
	G0008 Administration of Influenza Vaccine **ICD Code:** V0481 Need for prophylactic vaccination
	(Circle one) G9141 **or** 90470 Administration of H1N1 Influenza Vaccine _____ Dose 1 _____ Dose 2

(Seasonal Flu) Self Pay ONLY: Amount Collected $_____ Signature:_____
(If different that authorized person above)

H1N1 Influenza Vaccine ADMINISTRATION RECORD
(NO third party billing)

LHD name:_____
LHD address:_____
_____
Offsite location:_____
_____

NAME: _____

ADDRESS:_____
STREET CITY COUNTY STATE ZIP

BIRTHDATE: _____/_____/_____ **PHONE NUMBER:** _____
MONTH DAY YEAR

RACE: (Check ONE or MORE) ☐ **(W)** White ☐ **(B)** Black or African American ☐ **(N)** American Indian or Alaska Native

☐ **(A)** Asian ☐ **(H)** Native Hawaiian or Other Pacific Islander **ETHNICITY:** Hispanic or Latino **(Y)** Yes or **(N)** No

SEX: (Check ONE) ☐ Male ☐ Female

The health department may keep this record in a medical file. They will record what vaccine was given, when the vaccine was given, the name of the company that made the vaccine, the vaccine's special lot number, the vaccine injection site, the signature and title of the person who gave the vaccine, and the address where the vaccine was given.

I am not responsible for any charges for the H1N1 influenza vaccine or administration.

"I have read or have had explained to me the 2009-2010 Vaccine Information Statement (VIS) and understand the risks and benefits for the: (Check one box)

( ) 2009-2010 *Inactivated* ***H1N1 influenza vaccine, (*VIS dated 10/2/09)**

( ) 2009-2010 *Live****, Intranasal H1N1 influenza vaccine, (*VIS dated 10/2/09)**

X_____ **DATE:** _____
Signature of person to receive vaccine or person authorized to make the request (parent or legal guardian)

FOR HEALTH DEPARTMENT USE ONLY

Vaccine Manufacturer:_____ Vaccine Lot Number:_____
Injection Site:_____
Signature and Title of Provider: _____ **Provider# :**_____
NOTES: _____
_____

_____ Dose 1 _____ Dose 2

*LHD name*_____
*LHD address*_____
*Off-site Location*_____

PEF label OR

DOCUMENT#: _____

HID/LOC/SITE: _____

H1N1 Influenza Vaccine ADMINISTRATION RECORD

NAME: _____ **SOCIAL SECURITY#:** _____

ADDRESS: _____
STREET CITY COUNTY STATE ZIP

BIRTHDATE: _____/_____/_____ **PHONE NUMBER:** _____
MONTH DAY YEAR

RACE: (Check ONE or MORE) ☐ **(W)** White ☐ **(B)** Black or African American ☐ **(N)** American Indian or Alaska Native

☐ **(A)** Asian ☐ **(H)** Native Hawaiian or Other Pacific Islander **ETHNICITY:** Hispanic or Latino **(Y)** Yes or **(N)** No

SEX: (Check ONE) ☐ Male ☐ Female

DO YOU HAVE **MEDICAID** ? ☐ YES ☐ NO IF YES, **MEDICAID NUMBER**: _____

DO YOU HAVE **MEDICARE** ? ☐ YES ☐ NO IF YES, **MEDICARE NUMBER**: _____

DO YOU HAVE **HEALTH INSURANCE** ? ☐ YES ☐ NO

IF YES, **COMPANY NAME:** _____ **POLICY#:** _____

SUBSCRIBER'S NAME:_____**GROUP #:**_____

The health department may keep this record in a medical file. They will record what vaccine was given, when the vaccine was given, the name of the company that made the vaccine, the vaccine's special lot number, the vaccine injection site, the signature and title of the person who gave the vaccine, and the address where the vaccine was given.

"I have read or have had explained to me the 2009-2010 Vaccine Information Statement (VIS) and understand the risks and benefits for the: (Check one box)

( ) 2009-2010 *Inactivated* ***H1N1 influenza vaccine, (VIS dated 10/2/09)***

( ) 2009-2010 *Live,* ***Intranasal H1N1 influenza vaccine, (VIS dated 10/2/09***

☐ **ASSIGNMENT OF BENEFITS** I request that payment of authorized medical insurance benefits be made to the local health department listed above on behalf of name above, for services received. I also authorize the local health department to release medical information to Medicare, Other Third Payors (insurance carriers, Medicaid, etc.) and their agents to determine payment for services. **I will not be responsible for any charges for the H1N1 influenza vaccine or administration.**

X_____ **DATE:** _____

Signature of person to receive vaccine or person authorized to make the request (parent or legal guardian)

FOR HEALTH DEPARTMENT USE ONLY

Vaccine Manufacturer:_____Vaccine Lot Number:_____

Injection Site:_____

Signature and Title of Provider: _____ Provider# :_____

NOTES: _____

	ADMINISTRATION OF H1N1 Influenza Vaccine
	(Circle one) G9141 **or** 90470 Administration of Influenza Vaccine **ICD Code:** V0481 Need for prophylactic vaccination
	_____ Dose 1 _____ Dose 2

*LHD name*_____
*LHD address*_____
*Offsite Location*_____

PEF label OR

DOCUMENT#: _____

HID/LOC/SITE: _____

SCHOOL FORM

H1N1 Influenza Vaccine ADMINISTRATION RECORD

NAME: _____ **SOCIAL SECURITY#:** _____

ADDRESS: _____
STREET CITY COUNTY STATE ZIP

BIRTHDATE: _____/_____/_____ **PHONE NUMBER:** _____
MONTH DAY YEAR

RACE: (Check ONE or MORE) □ **(W)** White □ **(B)** Black or African American □ **(N)** American Indian or Alaska Native
□ **(A)** Asian □ **(H)** Native Hawaiian or Other Pacific Islander **ETHNICITY:** Hispanic or Latino **(Y)** Yes or **(N)** No

SEX: (Check ONE) □ Male □ Female

DO YOU HAVE **MEDICAID** ? □ YES □ NO IF YES, **MEDICAID NUMBER**: _____
DO YOU HAVE **MEDICARE** ? □ YES □ NO IF YES, **MEDICARE NUMBER**: _____
DO YOU HAVE **HEALTH INSURANCE** ? □ YES □ NO
IF YES, **COMPANY NAME:** _____ **POLICY#:** _____
SUBSCRIBER'S NAME: **GROUP #:**

Y N

□ □ Has your child had a previous H1N1 vaccine? ____ Nasal ____ Shot DATE:_____
□ □ Does your child have a serious allergy to eggs?
□ □ Does your child have any other serious allergies? Please list_____
□ □ Has your child ever had a serious reaction to a previous dose of flu vaccine?
□ □ Has your child ever had Guillain-Barre Syndrome (a temporary severe muscle weakness) within 6 weeks after receiving a flu shot?
□ □ Has your child been vaccinated with any vaccine (not just flu) within the past 30 days? Vaccine_____ Date_____
□ □ Does your child have any of the following: asthma, diabetes, disease of the lungs, heart, kidneys, liver, nerves, or blood?
□ □ Is your child on long-term aspirin or aspirin containing therapy (does your child take aspirin every day)?
□ □ Does your child have a weak immune system (HIV, cancer, or medications such as steroids or those used to treat cancer)?
□ □ Is your child pregnant?
□ □ Does your child have close contact with a person who needs care in a protected environment (example, someone who has recently had a bone marrow transplant)?

The health department may keep this record in a medical file. They will record what vaccine was given, when the vaccine was given, the name of the company that made the vaccine, the vaccine's special lot number, the vaccine injection site, the signature and title of the person who gave the vaccine, and the address where the vaccine was given.

"I have read or have had explained to me the 2009-2010 Vaccine Information Statement (VIS) and understand the risks and benefits for the: (Check one box)

( ) 2009-2010 *Inactivated* ***H1N1 influenza vaccine, (VIS dated 10/2/09)***
( ) 2009-2010 *Live,* ***Intranasal H1N1 influenza vaccine, (VIS dated 10/2/09)***

□ **ASSIGNMENT OF BENEFITS** I request that payment of authorized medical insurance benefits be made to the local health department listed above on behalf of name above, for services received. I also authorize the local health department to release medical information to Medicare, Other Third Payors (insurance carriers, Medicaid, etc.) and their agents to determine payment for services. **I will not be responsible for any charges for the H1N1 influenza vaccine or administration.**

X_____ **DATE:** _____
Signature of person to receive vaccine or person authorized to make the request (parent or legal guardian)

I **DO NOT GIVE CONSENT** to the Local Health Department and its staff for my child named at the top of this form to be vaccinated with this vaccine.
_____ **DATE**:_____
Signature of parent or legal guardian

FOR HEALTH DEPARTMENT USE ONLY

Vaccine Manufacturer:_____ Vaccine Lot Number:_____
Injection Site:_____
Signature and Title of Provider: _____ Provider# :_____
NOTES: _____

	ADMINISTRATION OF H1N1 Influenza Vaccine
	(Circle one) G9141 **or** 90470 Administration of Influenza Vaccine **ICD Code:** V0481 Need for prophylactic vaccination
	_____ Dose 1 _____ Dose 2

Influenza Vaccination Record

Provider: (name, address, phone)	
Full name / Nombre completo:	

Date of birth / Fecha de nacimiento: ___/___/___
m m d d y y / a a

Attention! / ¡Atención!

Keep this Vaccination Record for at least 1 year after your last vaccination. / Conserve este registro de vacunación hasta por lo menos 1 año después de recibir la última vacuna.

What if I think I am having a reaction to a vaccination?

- Contact your doctor or your local health department if you don't have a doctor
- Tell your doctor what happened
- Show your doctor this Vaccination Record
- You or your doctor should report the reaction to the **Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or http://vaers.hhs.gov**

¿Qué hago si creo que tengo una reacción a la vacuna?

- Contacte a su médico o al departamento de salud local si no tiene un médico personal
- Infórmele a su médico la reacción que tuvo
- Muéstrele al médico este registro de vacunación
- Usted o el médico debe reportar la reacción al **Sistema de Notificación de Reacciones Adversas a las Vacunas (VAERS) al 1-800-822-7967 o http://vaers.hhs.gov**

Influenza Vaccination Information

Vaccine	Dose	Lot Number	Manufacturer	Date
2009 H1N1 ..... Adjuvant	1st	.....		___/___/___ m m d d y y
2009 H1N1 ..... Adjuvant	2nd	.....		___/___/___ m m d d y y
2009–2010 Seasonal	1st			___/___/___ m m d d y y
	2nd			___/___/___ m m d d y y

***Reminder!* Return for a second dose! /**
***¡Recuerde!* ¡Regrese por la segunda dosis!**

☐ **2009 H1N1 influenza vaccine**
Vacuna contra la influenza H1N1 2009
Date/Fecha: ___/___/___ m m d d y y / a a

☐ **2009–2010 seasonal influenza vaccine**
Vacuna contra la influenza estacional 2009–2010
Date/Fecha: ___/___/___ m m d d y y / a a

H1N1 CODING & BILLING GUIDANCE
FOR LHD USE ONLY
September 30, 2009

- **H1N1 VACCINE IS FREE**
  - **You cannot charge anyone for the vaccine**

- **H1N1 ADMINISTRATION**
  - **LHDs cannot charge the patient for the administration**
  - **ANY vaccine provider receiving PHER funds cannot charge any fee to the patient regardless of their payer source, to include: deductible, co-pay & co-insurance.**
  - **Private, contracted vaccine providers may charge an administration fee to the patient and bill third parties as long as they are NOT receiving ANY PHER funds.**
  - **If XYZ has asked LHD for PHER funds to help defray costs to provide the vaccinations, and there is an agreement between both parties, then XYZ cannot charge the patient. However, they *may* be able to bill third parties.**

- **INSTRUCTIONS & FORMS**
  - **Instruction Memo including CPT/ICD-9 codes in draft form.**
  - **Administration/Consent forms are in final draft and will resemble the seasonal flu form.**
    - **Four forms have been developed:**
      - **One form for use in clinical setting or mass immunization(non-billing)**
      - **One form for use in clinical setting or mass immunization (billing 3rd parties)**
      - **One form combining H1N1 and Seasonal Flu**
      - **And a form for use in school setting**
  - **Vaccine Information Statements (VIS) have not been released by CDC at this time.**

- **BILLING OF ADMINISTRATION TO THIRD PARTY PAYERS**
  - ***Medicare: Free vs billing Medicare***

Q: Can a public health department bill a Medicare beneficiary for administration of flu shot even though they do not charge a non Medicare beneficiary?

A: Yes. Claims Processing Manual 100-04, Chapter 18, Section 10.2.5.2 found at this link: http://www.cms.hhs.gov/Manuals/IOM/list.asp

"Governmental entities (such as PHCs) may bill Medicare for pneumococcal, hepatitis B, and influenza virus vaccines administered to Medicare beneficiaries when services are rendered free of charge to non-Medicare beneficiaries."

- **LHD *may* bill third parties for administration:**
  - **Medicare Part B will pay same as seasonal flu ($18.77)**
  - **Preventive Medicaid will pay same as seasonal flu**
  - **Passport-pending confirmation**
  - **Humana Insurance-pending confirmation**

- **Other insurance to include (Part C) Medicare Advantage -LHD is responsible for benefit confirmation**

REMEMBER: ***the majority of your target population is not Medicare eligible*.**

- **LHDs not billing any third parties for administration:**
  - **No PEF is necessary**
  - **No entry into PSRS**
  - **Brief one page administration/consent form**
  - **Three year retention requirements**

- **LHDs who choose to bill third parties for administration:**
  - **Must meet collection, reporting & billing requirements of all third party payers**
  - **PEF is necessary**
  - **PSRS entry**
  - **Must hand-bill to any carrier not set up for electronic billing**
  - **Responsible for collection of billing information from patient**
  - **Responsible for collection of payment from third party payers**

TIME CODING

- **Preparedness employees**
  - **for regular time code to 821 or your normal cost center**
  - **for overtime code to 726**
- **All other employees**
  - **Code to 726 for any H1N1 activity**
- **Focus III cost center is 731**
  - **This should be effective Oct. 1 since the grant won't be awarded until 9/30**
  - **H1N1 services provided as a part of another clinical service is to be coded to 700. (WIC example)**
  - **H1N1 *only* services provided during regular clinic should be coded to 731.**
  - **H1N1 services provided as part of mass vaccination clinic to be coded to 731. (all disciplines)**

VOLUNTEER PROVIDERS/MRC

After the volunteer completes the registration process in KHELPS, the LHD completes the approval process.
Those three steps include:
1.) A background check,
2.) Verification of licensure (if a licensed person), and
3.) Completion of some paperwork (worker's comp, security agreement, badge, etc.) LHDs can complete a basic online verification of RN licensure on the KBN website.

If LHD will be billing 3rd parties you must have a provider number for each volunteer or contracted nurse. These provider numbers are requested through the Local Health Help Desk, localhealth.helpdesk@ky.gov or by phone at 502-564-7213, option 5.
If the health department needs a provider number for an independent contractor and/or a personal service employee contract. Please provide the name, job title and who will be responsible for the third party billing.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations

SHO # 09-011

September 24, 2009

Dear State Health Official:

As you may be aware, on July 24, 2009, Secretary Kathleen Sebelius renewed the declaration that a public health emergency exists nationwide involving novel influenza A (2009 H1N1), which will be referred throughout this document as 2009 H1N1. This declaration, first initiated on April 26, 2009, was made under the authority of section 319 of the Public Health Service Act. While this Secretarial declaration has no direct impact on the Medicaid program or the Children's Health Insurance Program (CHIP), the declaration supports a number of Federal emergency response activities and underscores the importance of ensuring that States are reviewing the operation and management of their Medicaid and CHIP programs to ensure that beneficiaries receive health care services related to 2009 H1N1 influenza effectively, efficiently and in the most appropriate settings. This letter provides guidance to States regarding these matters. This letter covers the following topics:

I. Vaccination Funding and Vaccine Administration
II. Presumptive Eligibility
III. Beneficiaries with Suspected or Confirmed 2009 H1N1 Influenza
IV. Provisions for Beneficiaries Receiving Services Through Managed Care Entities
V. People Receiving Home and Community-Based Waiver Services and State Plan Services
VI. Health Care Workforce Planning
VII. Administrative Funding for Activities Related to Education and Outreach
VIII. Emergency Medical Services Under Section 1903(v) of the Social Security Act

In addition to this guidance, the Centers for Medicare & Medicaid Services (CMS) will be available to provide ongoing technical assistance to States and will be offering an expedited State plan amendment (SPA) review/approval process when States request necessary modification(s) to their State plans related to 2009 H1N1. For up-to-date information about Federal emergency response and related activities during the period of this 2009 H1N1 influenza public health emergency, States, Medicaid and CHIP providers are directed to the Federal Government's Web sites at www.flu.gov and www.cdc.gov/h1n1flu/guidance.

In general, the coverage and other issues discussed below apply to all full-benefit Medicaid beneficiaries (including those whose benefits are funded through CHIP/Medicaid expansion programs). These are also applicable to beneficiaries in separate CHIP programs and the letter

identifies circumstances in which beneficiaries in separate CHIP programs are treated differently than Medicaid beneficiaries.

I. Vaccination Funding and Vaccine Administration

The 2009 H1N1 vaccine is currently in clinical trials. The two Federal Web sites referenced above, www.flu.gov and www.cdc.gov/h1n1flu/guidance will have the most up-to-date information about the vaccine.

(A) High-priority Populations

The Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC) have identified the following target groups to receive the 2009 H1N1 vaccine when it becomes available in mid-October 2009:

- **Pregnant women** because they are at higher risk of complications and can potentially provide protection to infants younger than 6 months of age who cannot be vaccinated;

- **Household contacts and caregivers for children younger than 6 months of age** because younger infants are at higher risk of influenza-related complications and cannot be vaccinated. Vaccination of those in close contact with infants less than 6 months old might help protect infants by "cocooning" them from the virus;

- **Healthcare and emergency medical services personnel** because they are at very high risk of exposure to the new H1N1 virus and because infections among healthcare workers can be a potential source of infection for vulnerable patients. Also, increased absenteeism in this population could reduce healthcare system capacity;

- **Children from 6 months through 18 years of age** because we have seen many cases of novel 2009 H1N1 influenza in children and they are in close contact with each other in school and day care settings, which increases the likelihood of disease spread;

- **Young adults 19 through 24 years of age** because we have seen many cases of novel 2009 H1N1 influenza in these healthy young adults and they often live, work, and study in close proximity, and they are a frequently mobile population; and,

- **Persons aged 25 through 64 years who have health conditions associated with higher risk of medical complications from influenza.**

(B) Vaccine Funding and Vaccine Administration

The vaccine itself will be purchased by the Federal Government. Information about vaccine distribution can be found on the CDC Web site at http://www.cdc.gov/H1N1flu/vaccination/statelocal/centralized_distribution_qa.htm.

While the vaccine will be free, providers will be allowed to charge a fee for the administration of the vaccine. Medicaid and CHIP programs will be responsible for covering the administration fee for eligible populations. States are encouraged to review the vaccine administration fees outside of the Vaccines for Children (VFC) program to ensure they are adequate to provide broad access to the 2009 H1N1 vaccine.

- While the purchase and distribution of the 2009 H1N1 vaccine will be outside of the purview of the Vaccine for Children program, States will still be required to reimburse the administration fee for the 2009 H1N1 vaccine for individuals under the age of 21 as part of the Medicaid Early and Periodic Screening, Diagnostic and Treatment program (EPSDT). Under the Medicaid EPSDT benefit, individuals under age 21 are entitled to vaccine coverage as recommended by ACIP, with payment for the vaccine and vaccine administration as specified in the State plan. In addition, States are required to inform all individuals under the age of 21 who have been determined to be eligible for Medicaid of the availability of EPSDT services including the need for age-appropriate immunizations against vaccine preventable diseases. Informing should also include a discussion of the benefits of preventive services and how to obtain those services. States may target "at risk" groups for specific informing (e.g., pregnant woman).

- For children covered in a separate CHIP program, coverage of ACIP-recommended vaccine administration is a requirement of well-baby and well-child care.

- For adults in the Medicaid program, 2009 H1N1 vaccine administration is a covered service when furnished by a participating provider under a "mandatory" section 1905(a) Medicaid benefit. Since hospital, physician and federally qualified health center/rural health clinic (FQHC/RHC) services are mandatory Medicaid benefits, 2009 H1N1 vaccine administration would be a covered service when provided by these participating providers. States should carefully review their State plans, and if necessary, submit State plan amendments to remove barriers to non-provider participation, and allow coverage of adult 2009 H1N1 vaccine administration by providers in settings that are considered "optional" Medicaid benefits (e.g., freestanding clinics, independent licensed non-physician practitioners). States should also review their State plan payment methodologies to ensure appropriate payment for vaccine administration. An expedited SPA review process is available.

  The Department of Health and Human Services is providing more than $1 billion to States for vaccine administration. States should ensure that Medicaid and other Federal funding sources are appropriately coordinated to prevent duplicate payments.

States should encourage Medicaid and CHIP enrollees to present eligibility information to vaccination and treatment sites to facilitate appropriate billing.

(C) Roster Billing for 2009 H1N1 Vaccine

Roster billing can substantially lessen the administrative burden on providers by allowing them to submit one claim identifying all eligible Medicaid and CHIP beneficiaries that receive the 2009 H1N1 vaccine on a given day. While we recognize that this could place additional administrative burdens and costs on the States if they have not previously designed their system to process roster billings, we encourage States to examine their ability to modify their systems and processes to accommodate roster billing for 2009 H1N1 vaccines, and any future mass immunization programs. The costs for implementing system changes and operations would qualify for the enhanced rate associated with the operation of the Medicaid Management Information System.

(D) 2009 H1N1 Vaccine HIPAA-Compliant Codes

CPT 90465-90474 are codes for vaccine administration. For coding (identifying) the 2009 H1N1 vaccine, States may wish to use the current CPT code 90663, which is a generic code for pandemic influenza virus vaccine.

(E) Providing Vaccinations in Additional Settings

To the extent that States have not done so already, States are encouraged to expand coverage for vaccine administration to a range of providers and settings, including non-traditional care sites, in order to efficiently and effectively provide vaccinations to large numbers of Medicaid and CHIP beneficiaries. These could include walk-in clinics at retail stores/outlets/pharmacies and school-based health centers/clinics. Other ways for States to consider expanding their capacity to cover/provide mass vaccinations would be to establish clinics under physician direction at schools. Note that Federal requirements pertaining to clinic services at 42 CFR 440.90 require that services be provided "under the direction of a physician." Physician direction can be met, in the case of vaccinations, through standing orders provided by the physician or other forms/mechanisms of indirect physician direction/supervision where the physician is not necessarily on-site. The physician must, however, assume professional responsibility for the service/vaccinations provided by those under his/her direction and be readily available for direction/consultation.

Depending on the State's current State Medicaid or CHIP plan, a SPA may be required to effectuate some of these options to expand provision of and access to 2009 H1N1 vaccinations. CMS will assure that such SPAs are acted upon promptly and expeditiously.

II. <u>Presumptive Eligibility</u>

Many of the individuals who are in priority categories for receiving 2009 H1N1 vaccinations are uninsured children and pregnant women who are eligible for Medicaid or CHIP but not enrolled. States have the option to provide Medicaid and CHIP services during a presumptive eligibility period. Presumptive eligibility provides immediate coverage to an individual while a formal eligibility determination is being made. Because of the time required to apply and to complete a determination for a child or pregnant woman, presumptive eligibility ensures that care is not

delayed while the individual is going through the eligibility determination process. In order to assure prompt diagnosis and treatment of 2009 H1N1 influenza cases, CMS encourages States to amend their Medicaid or CHIP State plans to provide a period of presumptive eligibility for children and pregnant women. States may not limit the populations of children and pregnant women to whom this option is applied (e.g., only to individuals with suspected or confirmed 2009 H1N1 influenza), except to define the income and ages of children (not to exceed age 19) to whom this option is applied. States may, however, limit the categories of entities it will permit to determine presumptive eligibility.

Under a presumptive eligibility option, qualified providers or other entities designated by the State determine presumptive eligibility based on preliminary information about the individual's family income. Payment to providers and Federal financial participation to the State is assured for services provided during the presumptive eligibility period. Federal requirements at sections 1902(a) and 1920 of the Act specify that States may provide ambulatory prenatal care during a presumptive eligibility period for pregnant women.

Under CHIP, requirements for States to offer CHIP coverage during a presumptive eligibility period for pregnant women can be found at section 2112(c) (as added by the Children's Health Insurance Program Reauthorization Act of 2009). States that offer coverage to children during a presumptive eligibility period are required to offer full Medicaid or CHIP coverage to children under age 19. Requirements for children are specified at sections 1902(a) and 1920A of the Act for Medicaid and at section 2107(e)(1)(D) for CHIP. The Medicaid implementing regulations can be found at 42 CFR 435.1100-1102 and the CHIP requirements related to presumptive eligibility are at 42 CFR 457.355. States with questions about implementing the option for presumptive eligibility in their Medicaid and/or CHIP program may contact CMS for technical assistance.

III. Beneficiaries with Suspected or Confirmed 2009 H1N1 Influenza

(A) Services

Full-benefit Medicaid and CHIP beneficiaries (adults and children) who are symptomatic with suspected or confirmed 2009 H1N1 influenza are entitled to be covered for medically necessary evaluation and services, including diagnostic testing, treatment and emergency care. These services are covered in a number of ambulatory and other settings that States are required to cover as part of the Medicaid and CHIP benefit packages. For Medicaid, these mandatory services include laboratory, hospital, physician, and FQHC/RHC services. For separate CHIP programs, services are determined by the health benefits coverage option that the State has elected. In both programs, mandatory treatment settings would include emergency room or hospital inpatient settings when appropriate for severe symptoms and complications of 2009 H1N1 influenza (e.g., for pneumonia and serious/life threatening conditions related to 2009 H1N1).

Under EPSDT services, Medicaid children under age 21 are entitled to coverage for any medically necessary diagnostic and treatment service that the State could elect in its approved State Medicaid plan, even if the State has not so elected for other Medicaid

beneficiaries. This would include services provided in additional settings that may not be available to adults under the State plan. Sections (E) and (F) below discuss how States can assure that services are available in alternative care settings.

(B) Standards of Care/Medical Necessity

During the period of this 2009 H1N1 influenza public health emergency, States, Medicaid and CHIP providers, including physicians and hospitals, are directed to the Federal Government's Web sites at www.flu.gov and www.cdc.gov/h1n1flu/guidance for the most up-to-date information to assist them in making medical necessity determinations and in providing services consistent with a professional level of care. States, Medicaid and CHIP providers are directed to these Web sites since they contain relevant, current information and standards of care for providers (and others) pertaining to 2009 H1N1 influenza.

(C) Cost Sharing for Covered Services

Copayments may serve as a deterrent to seeking timely care. Sections 1916(a)(2) and 1916A(b)(3)(B) of the Act, and 42 CFR 447.53(b) specifically exclude certain services from payment of a deductible, cost sharing or similar charge. These services include those provided to children under 18 years, pregnant women and emergency services. For beneficiaries in separate CHIP programs, under section 2103(e) of the Act, States may not impose cost sharing for children or pregnant women for preventive services, such as well-baby and well-child care which, as described in 2103(c), includes age appropriate immunizations such as 2009 H1N1.

(D) Prior Authorization for Drugs

Since the prompt use of antiviral drugs is generally medically necessary to be effective, CMS urges States not to require prior authorization for antiviral medications or other medications necessary to treat 2009 H1N1 influenza.

Where these drugs are prior authorized, the law requires that there must be a system in place to provide a response to a prior authorization request within 24 hours of the request, and the State must provide the dispensing of at least a 72-hour supply of a covered outpatient drug in an emergency situation as defined by the Secretary. The CDC recommends that a full 5-day treatment course of antivirals be prescribed and dispensed immediately for suspected 2009 H1N1 cases for those patients who are severely ill (hospitalized) and those patients who are ill with influenza-like illness and who are at the high-risk for influenza related complications among high-risk populations or with serious illness.

(E) Providers

To ensure access to care, States may consider reaching out to new providers to participate in the Medicaid program. In order to furnish and bill for services provided to Medicaid and CHIP beneficiaries, providers must enroll in the Medicaid and/or CHIP program.

This is done through the execution of an agreement between the State and the provider. Federal Medicaid regulations at 42 CFR Part 431 describes basic Federal requirements which must be met in such an agreement between the State and its providers. However, States are given broad discretion to include/impose additional requirements on providers in order to enroll in the program. Sometimes these additional requirements are quite lengthy and processing provider applications takes a long time. Therefore, we encourage States to consider streamlining provider applications to ensure that providers can provide 2009 H1N1-related services and can enroll promptly.

(F) Care Sites

To address the threat of the 2009 H1N1 influenza virus and ensure that the health care delivery system is appropriate to meet beneficiary needs, CMS encourages State Medicaid agencies to not only work with public health departments and other entities coordinating plans, but also to consider their options for expanding the sites where Medicaid and CHIP beneficiaries who are symptomatic and require 2009 H1N1 influenza-related services can receive care on an outpatient, ambulatory care basis. Medicaid and CHIP-funded care for eligible individuals with mild to moderate symptoms of 2009 H1N1 flu is available at clinics, physician offices, and FQHCs/RHCs. Such care could also be provided at alternate sites, as long as Federal and State requirements are met.

One of the goals of expanding capacity for providing appropriate ambulatory care/services is to divert individuals, including Medicaid and CHIP beneficiaries, who might otherwise utilize the emergency room, to more appropriate ambulatory settings. To this end, we encourage State Medicaid and CHIP agencies to work with State public health agencies, survey agencies, and providers, including hospitals, to notify/inform the general public and in particular Medicaid and CHIP beneficiaries that appropriate ambulatory care for the treatment of mild to moderate 2009 H1N1 flu symptoms is available and to identify where they might receive that care. Again, depending on the State's current State Medicaid or CHIP plan, a SPA may be required to effectuate some of these options to expand provision of and access to appropriate ambulatory care for 2009 H1N1 influenza-related symptoms.

(G) HIPAA-Compliant Codes for Diagnosis and Treatment of 2009 H1N1

HIPAA-compliant codes are used by providers and payers (including Medicaid and CHIP) to claim and reimburse for covered services. Effective October 1, 2009, a new ICD-9 diagnosis code for H1N1 influenza virus will be established to identify/code patients with suspected or laboratory confirmed 2009 H1N1 influenza. This code will enable providers and payers to identify, track, claim, and reimburse for covered services provided to persons who will/could be covered under title XIX.

IV. Provisions for Beneficiaries Receiving Services Through Managed Care Entities

To the extent that symptoms of suspected or confirmed 2009 H1N1 influenza are sufficiently severe that a prudent layperson might reasonably expect that the absence of immediate treatment

could result in imminent harm to health, managed care entities may not impose prior authorization or referral requirements prior to the assessment, diagnosis and treatment of Medicaid or CHIP beneficiaries presenting with such symptoms. In cases in which the prudent layperson test is not met, Medicaid and CHIP beneficiaries with flu-like symptoms may seek these services from their primary care provider or obtain any necessary referrals from their managed care plan. The Medicaid and CHIP programs should inform all managed care entities in the State of these policies.

V. People Receiving Home and Community-Based Waiver Services and State Plan Services

In the case of a 2009 H1N1 pandemic, continuity and quality of care for people with disabilities and older people with chronic diseases could be seriously impacted. An outbreak could result in a workforce disruption and could require sudden changes in both the types and location of services. States will be expected to take advantage of existing program flexibilities and respond quickly to changing health care needs and ensure provision of quality services.

States have existing flexibility to ensure continuity of services to people currently served under the section 1915(c) waiver program and State plan who require acute care. Under the 1915(c) waiver program, States can "hold" the waiver slot so that a waiver participant who has a short-term hospital or institutional stay can return to the waiver and receive needed community services – for which Medicaid will reimburse the Federal share (as long as the person still maintains Medicaid financial eligibility). Under the State plan, if a Medicaid beneficiary receiving home health care needs to go into a hospital, nursing facility, etc., then home health services may resume upon discharge, provided the beneficiary still meets the State's medical necessity criteria for the receipt of home health care.

States also have existing flexibility to respond to sudden changes in need for services. For example, if a caregiver becomes ill and unable to provide supports, States have flexibility under both the 1915(c) and State plan programs to ensure availability of supports. For people already enrolled in the 1915(c) Home and Community-Based Services (HCBS) waiver program, States have the authority and flexibility (and a statutory responsibility) to adjust the waiver participant's plan of care to respond to changing situations in the participant's life that may require additional services. Any services covered under the approved waiver and authorized by the State are eligible for Federal Medical Assistance Percentage (FMAP). If the State determines that additional services, not already authorized in the approved waiver, are needed, the State may request an amendment to the waiver to add additional services or to serve additional persons. CMS is developing mechanisms through its Web-based waiver application to further expedite the processing of emergency requests from the waiver programs, in the event of a 2009 H1N1 pandemic.

For people receiving services under the Medicaid State plan, if a primary caregiver for a beneficiary is ill and unable to provide care, CMS expects that the provider agency would have an "emergency" plan in place to continue to furnish the services needed by the beneficiary. The "emergency" plan must be communicated to the beneficiary in advance of an emergency and may include use of an online worker registry or replacement staff from the agency. We would

expect the State to determine whether all the provider agencies furnishing services have an emergency plan in place and that it has been communicated to the beneficiary and any representative. In addition, it should be noted that the regulation governing section 1915(j) of the Social Security Act (the self-directed personal assistance services State plan option at 42 CFR 441.464(d)(2)(xiii) and 42 CFR 441.468(a)(4), includes a requirement that a beneficiary has a "back-up" plan in the event a service provider is unable to furnish a needed service and that the plan is made a part of the participant's service plan. Finally, the regulation governing section 1915(j) also includes a requirement for a risk assessment of each potential risk to the participant and the risk management plan that will mitigate any identified risks not assumed by the participant.

VI. Healthcare Workforce Planning

Healthcare providers, including inpatient facilities, medical offices, clinics, home health agencies and others will play a crucial role in the event of an H1N1 pandemic this fall. Planning is critical, and CMS urges States to work with other state agencies to encourage healthcare providers to plan for workforce protection and business continuity.

Preparation checklists, toolkits, and guidelines that will assist healthcare providers and service organizations in planning for a pandemic outbreak can be found at http://www.flu.gov/plan/healthcare/index.html. CMS encourages States to include this information in communication to providers about 2009 H1N1.

VII. Administrative Funding for Activities Related to Education and Outreach

States will continue to have the use of Medicaid and CHIP administrative match for beneficiary and provider education and outreach. CMS encourages States to ensure that Medicaid and CHIP beneficiaries and providers are aware of the availability of the 2009 H1N1 vaccine, understand where beneficiaries may go to receive services, the procedures for receiving those services and contacts for obtaining additional information. Outreach should be aided by Centers for Disease Control and Prevention funding awarded to States through Public Health Emergency Response Program. This funding was intended to provide financial resources for implementing a mass vaccination campaign at the State, local, tribal, and territorial levels.

VIII. Emergency Medical Services Under Section 1903(v) of the Social Security Act

Individuals who are entitled only to Medicaid coverage of emergency medical services under section 1903(v) include those who meet all other Medicaid eligibility requirements such as State residency, income, categorical status, but are undocumented or lawfully residing in the U.S. but subject to the "5-year waiting period." Emergency medical services related to H1N1 influenza are available to these individuals consistent with section 1903(v).

IX. Coordination with Other Federal Resources and Programs

States should ensure that their Medicaid and CHIP plans for the 2009 H1N1 preparation and response activities are consistent and coordinate with other Federal funds such as the Public

Health Emergency Preparedness (PHEP) and Public Health Emergency Response (PHER) cooperative agreements from CDC, and the Hospital Preparedness Program (HPP) from the Assistant Secretary for Preparedness and Response (ASPR).
In conclusion, CMS understands that States are already working on these and many other 2009 H1N1-related issues, and we look forward to partnering with you to ensure all eligible beneficiaries have access to timely care. We hope this letter is a helpful beginning. If you have any questions, please contact Ms. Krista Drobac at (202) 205-3067 or Krista.Drobac@cms.hhs.gov.

Sincerely,

/s/

Cindy Mann
Director

cc:

CMS Regional Administrators

CMS Associate Regional Administrators
Division of Medicaid and Children's Health

Ann C. Kohler
NASMD Executive Director
American Public Human Services Association

Joy Wilson
Director, Health Committee
National Conference of State Legislatures

Matt Salo
Director of Health Legislation
National Governors Association

Debra Miller
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Christine Evans, M.P.H.
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Executive Director
National Academy for State Health Policy

CDC
H1N1 Vaccination Campaign
Planning Checklist
8/1/09

Note:

This is a DRAFT document. The final version will be posted at CDC H1N1 Vaccine planning web page in the near future.

Introduction:

This document is intended for state and local planners. Its purpose is to outline main planning actions. It is not meant to be exhaustive and additional more detailed guidance is or will be available on specific topics. Within each state, the checklist should be tailored to distinguish state and local responsibilities.

General:

- ☐ Ensure clear delineation of responsibilities and regular communication between involved programs at state level (Preparedness, Immunization, others)
- ☐ Clear delineation of responsibilities and regular communication between state and local programs

Target and Priority Groups:

- ☐ Determine estimated size in jurisdiction of target and priority groups as defined by ACIP (http://www.cdc.gov/h1n1flu/vaccination/acip.htm).
- ☐ Develop plans which may include public health sponsored clinics or vaccination via private sector vaccinators to reach each target and priority group.

Vaccination by Private Sector Partners:

- ☐ Meet with and disseminate information through medical societies, hospital associations, healthcare provider professional organizations
- ☐ Conduct mail outs or blast fax information to lists of providers obtained from licensing boards or medical societies
- ☐ Identify clinical providers and health systems interested in providing H1N1 vaccine (e.g. pediatricians, including non-VFC providers, family physicians, Obstetrician/Gynecologists, internists, HMOs, hospitals and other health care facilities)
- ☐ Identify community immunizers interested in administering H1N1 vaccine
- ☐ Develop a pre-registration process so providers can indicate interest, receive information updates as available, and provide information needed for vaccine delivery
- ☐ Provide easily-locatable information on health department website for vaccinators, indicating what role they might play in given state/jurisdiction and how they can obtain information
- ☐ Use federal language, once available, to develop provider agreement between providers and public health

- ☐ Contact large businesses regarding plans for worksite vaccinations
- ☐ Contact college and university health centers

Vaccination by Other Partners:

Collaborate with the following systems and facilities, where applicable, as above to ensure vaccination of populations served or associated with them:

- ☐ Military bases to develop plan for military dependants
- ☐ VA clinics
- ☐ IHS clinics and tribal clinics
- ☐ FQHCs and RHCs (including reaching out to state Primary Care office and Primary Care Association)

Public Health Vaccination Clinics:

Clinics that are conducted, organized, or sponsored by public health.

- ☐ Determine populations that will be targeted for vaccination via large scale/public health sponsored clinics
- ☐ Identify clinic sites (number, locations, points of contact, alternative sites, accessibility)
- ☐ Estimate size and type (target and priority groups) of population to be served per site
- ☐ Determine staffing needs, and sources of staffing
- ☐ Develop plans for staffing, including identification of sources of volunteers and development of MOAs with relevant organizations.
- ☐ Initiate contracts with personnel agencies or community vaccinators to provide staff or organize/conduct clinic
- ☐ Define process to allow healthcare workers from other jurisdictions to vaccinate if necessary

Coordination of Vaccine Distribution:

- ☐ Determine overall relative allocations for public health clinics, including school-located vaccination, clinical providers, and other private sector providers (e.g. community immunizers, retail providers)
- ☐ As part of pre-registration or registration process, collect number of influenza doses administered previous year, where applicable, to help determine provider capacity for administering influenza vaccine
- ☐ Determine plan for allocating vaccine (e.g. partial shipments to all providers, sequential shipments to sets of providers)
- ☐ Develop staffing plan for entry of data into VACMAN
- ☐ Develop plan for provider practices unable to accommodate minimum shipment size (internal distribution, limiting vaccine to larger sites)

	☐ Develop plan for tracking vaccine usage by vaccinators to ensure vaccine supply is adequately directed where needed.
Vaccination of Healthcare Workers and EMS:	☐ Develop agreements with hospitals to delegate responsibility for vaccination of staff, and determine size of staff (total and staff with direct patient contact). ☐ Collect required information (e.g. shipping address, contact persons, etc.) for vaccine delivery ☐ Develop plan for outpatient providers (e.g. they may receive vaccine directly through centralized distribution, or if not among the first to receive vaccine may pick up at defined location) ☐ Develop plan for vaccinating EMS
Vaccination of School-aged Children:	☐ Make connections with education partners at state level ☐ Make connections with education partners, including school districts, at local level; create a list of schools/school districts willing to participate in school-located clinics ☐ Develop plans for staffing school-located clinics, including identification of sources of volunteers and development of MOAs with relevant organizations ☐ Develop informational materials for parents ☐ Work with local legal advisors to design consent forms ☐ Develop plans to distribute and maximize return of consent forms where applicable (i.e., if school clinics during school hours and without parents present are planned) ☐ Ensure VIS is provided to parents for each vaccination dose ☐ Develop plan to inform and obtain support of principals, teachers, and parent organizations ☐ Develop plan for informing and obtaining support from physicians in the community about school-located vaccination
Tribal Populations:	☐ Include IHS and tribal planners in finalizing vaccinations plans ☐ Ensure tribal populations are included in state vaccine allocation plans
Hard-to-reach and Vulnerable Populations:	☐ Define hard to reach populations ☐ Estimate size of populations

- ☐ Develop plan for reaching these populations and/or transporting to clinic sites
- ☐ Develop MOAs with public agencies, volunteer organizations, and others to reach these populations

Communications:

- ☐ Ensure clear communication about implementation of target and priority group recommendations and need for second dose
- ☐ Identify the varied audiences that need to receive audience-specific vaccine, vaccination, and vaccination site information and instructions
- ☐ Involve local stakeholders and/or key audience liaisons in shaping outreach strategies
- ☐ Identify language and cultural barriers and plan for addressing
- ☐ Plan testing of messages for receptivity, understanding.
- ☐ Create MOAs with channels for communication (e.g., print media/local papers, community and social or religious networks, commerce or local business partners
- ☐ Determine best means for targeting communication broadly to different ethnic and socioeconomic populations (Media, clinician outreach, websites or new media)
- ☐ Reach out to widely diverse local partners, volunteer groups and other NGOs with specific instructions and technical support on how to help disseminate messages and aid the general public in accessing vaccination sites.
- ☐ Plan information communication network throughout agencies at state and local levels to ensure coordination of messages
- ☐ Conduct ongoing assessment of strategies, and adjust messages as needed.

Large Scale Clinic Planning:

See guidelines at http://www.cdc.gov/h1n1/vaccination

General:

- ☐ Determine cold storage status at site
- ☐ Determine status of communications equipment
- ☐ Develop procedure for receiving and accounting for vaccine
- ☐ Develop site layout, patient flow, job descriptions, equipment needs
- ☐ Develop plan to provide ID to clinic staff
- ☐ Develop plan for responding to medical emergencies or adverse events (e.g. fainting)

- ☐ Develop plan for data collection
- ☐ Develop process for vaccination of non-English speakers (identify language needs and needed staffing)
- ☐ Ensure information on return date for second dose is provided
- ☐ Contact information for staff updated and available
- ☐ Training materials developed, including just in time training plan
- ☐ Contingency plans in the event of absenteeism
- ☐ Develop plan for advertising clinics to public and potential vaccinators

School-located Clinics:

- ☐ Address issues specific to vaccination of children (flow from classroom to vaccination)
- ☐ Plan for consent related issues at time of clinic (verifying identity of consented child when parent is not present)

Doses Administered Tracking:

- ☐ Determine data collection system and method for reporting minimum required data elements
- ☐ Define local data collection needs
- ☐ Distribute educational materials to vaccine administration sites
- ☐ Develop staffing plan and training for data collection, entering and forwarding at public clinics and at local and state health departments
- ☐ Determine equipment needs at all data collection and forwarding sites.

Safety Monitoring:

- ☐ Disseminate information to vaccinators on VAERS reporting
- ☐ Operational statewide network to provide technical information and technical aid to and to receive notification of adverse events from healthcare providers
- ☐ Plan use of vaccinee card (may be provided by CDC) with data of vaccination, 1st dose/2nd dose, lot number, return date for 2nd dose, VAERS information

Legal:

- ☐ Contact primary public health counsel to determine which allied health professionals are legally permitted to administer vaccine, to what types of patients, and under what conditions.
- ☐ Ensure dissemination/explanation of PREP Act information

For state and local jurisdictions where at least some vaccine will be shipped to a central receiving site and repackaged for shipping to other sites/providers:

General:	☐ Develop system to track inventory from receiving site to further points of distribution to be able to replenish supply in timely manner
Vaccine Receiving Sites:	☐ Staff responsibilities with respect to vaccine receipt defined. ☐ Staff needs for receiving, storing, breakdown, repackaging calculated (taking into account absenteeism) ☐ Training materials developed
Storage and Handling:	☐ Ensure adequate storage space for both refrigerated (preloaded syringes and multi-dose vials of vaccine and possibly, adjuvant) and non-refrigerated supplies
Transportation:	☐ Plan for transporting vaccine from receiving site o distribution sites ☐ Contingency plan for transportation ☐ Source and number of transportation staff identified (taking into account absenteeism) ☐ Training materials developed.
Security:	☐ Security at receiving sites, in transport to administration sites, and at administration site ☐ Contingency plan in place for unexpected disruption at administration site ☐ Staffing for security identified ☐ Training materials developed

Guidelines for Large Scale Vaccination Clinics

Considerations and Guidance for State and Local Planning for Emergency, Large-Scale, Voluntary Administration of Influenza Vaccine

Introduction

The recommended guidelines for implementation of a voluntary vaccination clinic are meant to support existing emergency vaccination clinic plans that state or local public health authorities have developed.

Large-Scale Vaccination Clinic Organization and Personnel Estimates

The following section addresses the different activities needed for the administration of influenza vaccine as well as examples of personnel estimates for clinic staffing. The examples could be expanded or contracted, as needed, to address changes in vaccination administration goals for different population areas. The example staffing estimates were arrived at by: 1) review of previous large-scale-clinic models and publications, 2) computer modeling for clinic flow and output estimates with different example staff numbers. Parameters of low and high completion times for specific activities within the clinic were estimated within the model. The time requirement for these activities may differ depending upon the overall demands placed on the vaccine clinic delivery system and could require adjustment of staffing estimates. State and local planners should evaluate these activity time estimates and consider what staffing or flow adaptations may be needed to accommodate increases or decreases in activity time requirements.

The numbers shown in the tables below are examples of the human resources needed with the above clinic assumptions and configuration. Alterations in the assumptions regarding clinic activity time estimates and staffing requirements can be explored to determine ways to further maximize clinic output and human resource utilization. Although staff numbers may vary depending upon the assumptions and clinic output requirements, the general tasks that must be addressed within the clinic (patient education, screening, l counseling, vaccination, etc.) would not change.

(e.g., physicians, nurses, and other staff) in such a manner that will maximize patient flow-through for target vaccination goals. Conversely, this software program may also be

used to determine maximum vaccination output that may be achieved with different human resource estimates.

The example models as outlined assumes that clinics can be operating at near full efficiency to meet vaccination goals once the decision to offer voluntary vaccination is made. Planners may vary the vaccination rate per hour based on their own experience.

Vaccinations Administered
Clinic Estimate with 4 Vaccination Stations

Vaccination Clinics (VC)	1 clinic site	More sites could be added to accommodate larger population bases
Vaccination Stations (VS)	4VS per shift 1 vaccinator per station 0.5 to 1 vaccine preparer per station (who can also alternate vaccinating) 8 vaccinators/vaccine preparers per shift	
Hours of Operation	At a minimum **16** hours/day	Consider expanding hours for higher daily output or to address overflow
Vaccination Delivery	~ 30 vaccinations per VS/ hour ~ 120 vaccinated/hr/VC ~1900 per day/VC ~19,000 vaccinated in ~ 10 days	30 vaccinations per VS/hour allows for variations caused by vaccinator rotation, resupply requirements, completing vaccination card, and other considerations

Breakdown of Clinic Personnel for Vaccination Clinic with 4 Vaccination Stations

Position	Number per 8-h Shift	Number per 16-h Day	Experience
Forms (VIS) Distribution+	2	4	Nonmedical
Orientation/Information	2	4	Nonmedical
Medical Screeners	1	2	Medical: nurse
Clinic Flow; Reviewer/Forms Helpers	4	8	Nonmedical: to assist with forms completion, collection, and clinic flow
Vaccinators	4	8	RNs, LPN, others as dictated by state laws
Vaccine Preparer/Supply to VS	4	8	LPN, MT
Exit Review	2	4	RN or public health person for questions/instruction/observation and form verification
Medical Records/Data Entry	5	10	Nonmedical, vaccine info and doses administered data processed
Clinic Manager	1	2	Nonmedical Public Helath/Imm Programs Personnel
Supply Manager	2	4	Nonmedical
Security	2	4	Non-public health resource
Translator (not counted in total clinic staffing estimates)	At least one per major language per shift	Unknown	Language fluency with training
Float Staff	1	2	Nonmedical volunteers
EMT	On call		Medical
IT Support	On call		Nonmedical
Total Personnel	**29**	**58**	**(does not include translators)**

Vaccinations Administered
Clinic Estimate with 8 Vaccination Stations

Vaccination Clinics (VC)	1 clinic site	More sites could be added to accommodate larger population bases
Vaccination Stations (VS)		8 VS per shift 1 vaccinator per station 0.5 to 1 vaccine preparer per station (who can also alternate vaccinating) 16 vaccinators/vaccine preparers per shift
Hours of Operation	At a minimum **16** hours/day	Consider expanding hours for higher daily output or to address overflow
Vaccination Delivery	~ 30 vaccinations per VS/ hour ~ 240 vaccinated/hr/VC ~ 5000 per day/VC ~38,000 vaccinated in ~ 10 days	30 vaccinations per VS/hour allows for variations caused by vaccinator rotation, resupply requirements, completing vaccination card, and other considerations

Breakdown of Clinic Personnel
For Vaccination Clinic with 8 Vaccination Stations

Position	Number per 8-h Shift	Number per 16-h Day	Experience
Forms (VIS) Distribution+	3	6	Nonmedical
Orientation/Information/	3	6	Nonmedical
Medical Screeners	1	2	Medical: nurse
Clinic Flow; Reviewer/Forms Helpers	7	14	Nonmedical: to assist with forms completion, collection, and clinic flow
Vaccinators	9	18	RNs, LPN, others as dictated by state laws
Vaccine Preparer/Supply to VS	8	16	LPN, MT
Exit Review	4	8	RN or public health person for questions/instruction/observation and form verification
Medical Records/Data Entry	8	16	Nonmedical, vaccine info and doses administered data processed
Clinic Manager	1	2	Nonmedical Public Helath/Imm Programs Personnel
Supply Manager	2	4	Nonmedical
Security	4	8	Non-public health resource
Translator (not counted in total clinic staffing estimates)	At least one per major language per shift	Unknown	Language fluency with training
Float Staff	2	4	Nonmedical volunteers
EMT	1	2	Medical
IT Support	On call		Nonmedical
Total Personnel	**53**	**106**	**(does not include translators)**

CDC Guidelines for Large-Scale Influenza Vaccination Clinic Planning

To facilitate the most efficient and safe delivery of available vaccine via large community clinics, these recommendations and guidelines have been developed to assist with planning large-scale influenza vaccination clinics by public and private vaccination groups. Ideally, plans from private and public groups should be shared to identify best practices, avoid unnecessary overlapping of services, and maximize the effective and efficient delivery of influenza vaccinations.

This document provides general guidance to help ensure smooth operations at large-scale vaccination clinics under 8 major headings:

1. Leadership roles
2. Human resource needs
3. Vaccination clinic location
4. Clinic lay-out and specifications
5. Crowd management outside of the clinic
6. Crowd management inside of the clinic
7. Clinic security
8. Clinic advertising

Leadership Roles

- Designate local clinic leaders for overall vaccination campaign operations and leaders for communications systems from both the public and private sectors
- Designate a clinic manager and a team leader and backups to coordinate supplies, logistics, clinic personnel, and to support functions

Human Resource Needs

- Secure staff to fill the positions of greeters-educators, priority client screeners, forms' support personnel, medical screeners, clinic flow controllers, vaccination assistants, vaccination administrators, data collectors/enterers, security and emergency medical personnel
- Meet the language needs of the community using multi-lingual staff
- Prepare staff members to know and execute their responsibilities and be able to correctly answer questions from clients
- Cross-train staff members, if possible, to enable flexibility in meeting needs at various stations as demands fluctuate
- Make provisions for surge capacity staffing, particularly at clinic opening time, where pre-scheduling will not be done or large numbers of unscheduled clients are anticipated
- Request surge capacity staff from out-of-area city/county agencies and health departments, local private nursing agencies, local nursing associations, local law enforcement, local medical community, health care worker and pharmacy students, volunteer groups and personnel working at the retail stores/corporations that might be used as the clinic sites

- Ensure staff well-being by scheduling times for rests and snacks in a designated area

Vaccination Clinic Location

- Seek out school gyms, churches, auditoriums, theaters or other large covered public spaces accessible to the elderly and persons with disabilities
- Ensure proximity to population centers and mass transit, ample parking, separate entry and exit doors, adequate lighting and heating, functional and accessible restrooms, and adequate space for all clinic functions such as screening, registration, vaccine storage, vaccination, and staff breaks
- Select a facility with space for reasonably large and well-delineated covered gathering areas outside and inside of the clinic

Clinic Lay-Out and Specifications

- Set up for unidirectional client flow from an external gathering area → eligibility screening area (multiple stations) → clinic entrance → facility waiting area(s) → form completion /question and answer area (multiple stations) → medical screening/treatment area (as needed) → vaccination area (multiple stations) → post-vaccination observation area → exit at a location distant from the entrance – (see Example of Large Scale influenza Vaccination Clinic attached)
- Use liberal amounts of rope, stands and signs in multiple languages, as needed, in outside waiting area(s) and inside clinic to delineate routes for clients to follow from station to station
- Provide seating for clients at each vaccination station and one or more vaccination stations with surrounding screens where over-clothed clients can discreetly bare their arms for vaccination
- Section off private area(s) where clients who experience acute adverse events after vaccination or who have medical problems can be evaluated and treated
- Ensure the presence of an onsite emergency medical kit and a physician, emergency medical technician (EMT), pharmacist, or nurse certified in basic cardiopulmonary resuscitation who can administer treatment for allergic reactions and address urgent medical problems

Crowd Management Outside of the Clinic

- Schedule staff to arrive 1 to 2 hours before clinic opening time to welcome and screen clients even if pre-scheduling is being used
- Arrange accommodations for special-needs clients (e.g., persons with disabilities, very advanced age or fragility) for expedited access into the clinic

- Direct arriving clients into several lines and use numerous signs and announcements to clarify who falls into high-risk groups
- Communicate the number of vaccine doses available at the clinic to the clients
- Instruct clients to assess their eligibility to receive vaccination by reviewing the CDC, or similar, self-screening form; provide language translation services where necessary
- Update clients on their estimated waiting times to be screened
- If vaccine supplies are limited and vaccine is being prioritized for certain groups, inform waiting clients that high-risk populations only will be served
- Schedule additional screeners to reduce crowd size and waiting times by rapidly identifying and retaining high-risk clients and dispersing non-priority individuals
- Distribute Vaccine Information Statement (VIS) and other educational or necessary clinic forms to clients as they enter into the clinic
- Provide clients who cannot be served for lack of vaccine an up-to-date listing of alternative clinics providing vaccinations

Crowd Management Inside of the Clinic

- Vaccinate clients in the order of their arrival (consider numbered tickets)
- Arrange accommodations for special-needs clients (e.g., persons with disabilities, very advanced age or fragility) to receive expedited vaccination – consider a dedicated vaccination line
- Communicate clinic updates and wait times for vaccination so that clients are free to leave and return to be vaccinated
- Provide entertainment materials, TV and/or refreshments if wait times are anticipated to be long
- Assist clients in completing required forms (e.g., consent forms**,** vaccination cards and/or other required forms) by having sufficient support staff available
- Utilize runners to keep staff stocked with ample supplies so that they can remain at their stations
- Maintain a steady flow of clients through the clinic so that vaccinators are never without a client at their stations; redirect clients to other stations if bottlenecks occur
- Vaccinator assistants fill syringes with vaccine at the time of vaccination only preparing just enough vaccine and prefilled vaccine syringes to meet the clinic's needs on an ongoing basis; never pre-fill before clinic opening hours
- Discard any vaccine-filled syringes remaining after the clinic closes
- Provide adequate facilities (e.g., waiting areas, restrooms, water) to meet the needs of the clients

Clinic Security

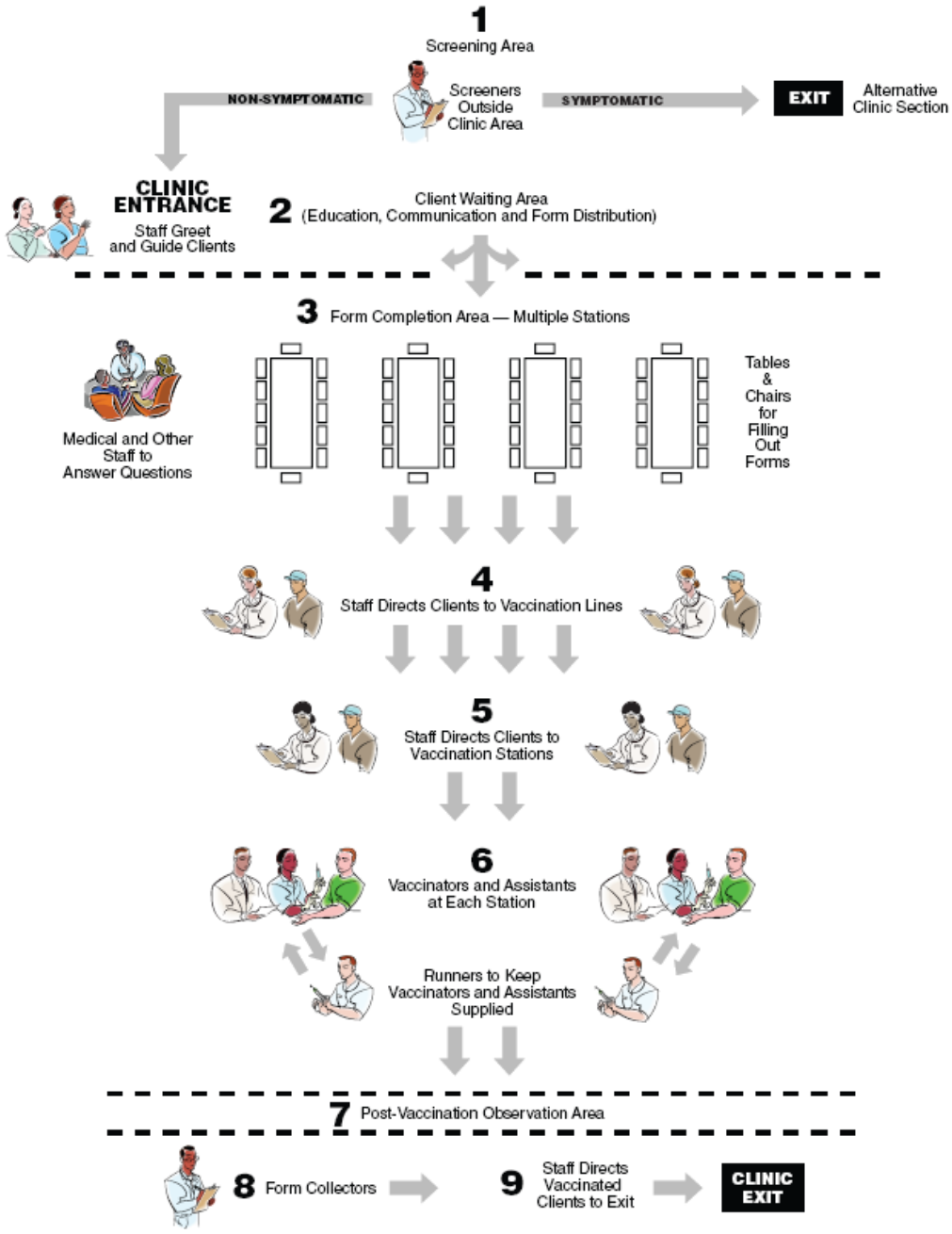
- Require all staff to wear identification cards color coded for their job functions

- Consider using uniformed presence to act as security and assist in managing crowds
- Employ security personnel to monitor the mood of waiting crowds and communicate deteriorating situations to the clinic manager
- Secure the vaccine and protect clinic staff and their valuables
- Recruit local volunteers familiar to clinic customers since they may be especially effective in diffusing crowd-related tension

Clinic Advertising

- Use multi-lingual and multimedia channels to widely post clinic purpose, dates, locations, times, and which populations will be served
- Provide instructions on how to set up appointments via telephone, in person, or other systems if pre-scheduling will be used
- Know how much vaccine is available for a scheduled clinic and how to reallocate vaccine through centralized or individual clinic efforts to meet the acute needs of other providers
- Recognize that scheduling may be overwhelmed and therefore not be maintainable or able to meet clients' needs during a time of severe vaccine shortage; direct clients to other facilities as required

Example of Large Scale Influenza Vaccination Clinic



REFERENCES

These vaccination clinic planning considerations are a compilation of concepts and practices from many sources – published, unpublished and personal communication.
Published sources:

- Prevention and Control of Influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP)
- General Guidelines for Smallpox Vaccination Clinics:
- Guidelines for Large Scale Vaccination Clinics:
- HHS Pandemic Influenza Plan

Unpublished draft document sources

- Community-Based Mass Prophylaxis: A Planning Guide for Public Health Preparedness. October 2004. Agency for Healthcare Research and Quality, Rockville, MD.
- General Guidelines for Pandemic Influenza Vaccination Clinics; Health Services Research and Evaluation Branch, NIP, CDC
- Pandemic Influenza: Clinic Preparation Checklists; Health Services Research and Evaluation Branch, NIP, CDC
- State and county health pandemic influenza preparedness plans; selected states
- State, county and city after action reports on exercises of mass prophylaxis and immunization plans; selected states

Personal Communication

- Community Vaccinators Working Group members Department of Health and Human Services Centers for Disease Control and Prevention

- Page last updated October 17, 2006
- Content Source: Coordinating Center for Infectious Diseases (CCID)
- National Center for Immunization and Respiratory Diseases (NCIRD)

- Clinical Description & Lab Diagnosis
- Free Flu Materials
- Seasonal Influenza and Staph Infections
- 2008 National Influenza Vaccination Week (NIVW)
- Flu Activity & Surveillance
- Training
- References & Resources

INFO FOR SPECIFIC GROUPS

OTHER FLU WEBSITES

- Avian Flu
- Canine Flu
- Pandemic Flu
- Swine Flu

- Home
- Policies and Regulati

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September 21, 2009

KENTUCKY PUBLIC HEALTH ADVISORY: NOVEL INFLUENZA A (H1N1) VIRUS INFECTION

Modifications of Existing CDC Recommendations about Infection Control Precautions, including Facemask and N95 Respirator Use, for Healthcare Personnel (HCP)

The Kentucky Department for Public Health (DPH) recommends the following modifications to the interim guidance and interim recommendations from the Centers for Disease Control and Prevention (CDC) for the care of patients with novel H1N1 influenza in all inpatient, outpatient, and pre-hospital healthcare settings:

- Patients with a confirmed, probable or suspected case of novel H1N1 influenza can be cared for with both standard and droplet precautions, rather than airborne precautions. Such patients *may* be placed in private rooms, rather than negative pressure rooms, with appropriate use of gloves, facemasks (e.g. *surgical* masks), gowns and hand washing by HCP. Face shields or eye protection should be used, as indicated, for patient care activities with risk for exposure to blood, body fluids, secretions or excretions. Patients on droplet precautions who must be transported or are likely to come into contact with the general public should wear a facemask if tolerated and follow procedures for respiratory hygiene / cough etiquette.
- Current use of N95 respirators or higher-level respirators should be limited and confined to instances of direct airway manipulation (e.g., bronchoscopy, intubation, nasopharyngeal suction).
- If N95 respirators are either not available or in short supply, please follow the CDC **Interim Domestic Guidance on the Use of Respirators to Prevent Transmission of SARS**, May 3, 2005: http://www.cdc.gov/ncidod/sars/respirators.htm .

These Kentucky modifications of current CDC recommendations are consistent with World Health Organization recommendations and Canadian guidelines for care of cases of novel H1N1 influenza. Other states have also implemented similar modifications since May 2009. These Kentucky modifications enable the practicable implementation of respiratory protection programs during the current influenza pandemic, considering that equipment and resource availability may be limited.

These Kentucky modifications should also be appropriate for all inpatient, outpatient and pre-hospital healthcare settings with a confirmed, probable or suspected case of seasonal influenza.

Healthcare personnel should consistently practice hand hygiene and respiratory hygiene.

DPH will periodically review and update this guidance as new scientific findings are published.

Surgical Mask vs N95 Respirator for Preventing Influenza Among Health Care Workers: A Randomized Trial

Mark Loeb; Nancy Dafoe; James Mahony; et al.

JAMA. published online Oct 1, 2009; (doi:10.1001/jama.2009.1466)

http://jama.ama-assn.org/cgi/content/full/2009.1466v1

Surgical Mask vs N95 Respirator for Preventing Influenza Among Health Care Workers

A Randomized Trial

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Context Data about the effectiveness of the surgical mask compared with the N95 respirator for protecting health care workers against influenza are sparse. Given the likelihood that N95 respirators will be in short supply during a pandemic and not available in many countries, knowing the effectiveness of the surgical mask is of public health importance.

Objective To compare the surgical mask with the N95 respirator in protecting health care workers against influenza.

Design, Setting, and Participants Noninferiority randomized controlled trial of 446 nurses in emergency departments, medical units, and pediatric units in 8 tertiary care Ontario hospitals.

Intervention Assignment to either a fit-tested N95 respirator or a surgical mask when providing care to patients with febrile respiratory illness during the 2008-2009 influenza season.

Main Outcome Measures The primary outcome was laboratory-confirmed influenza measured by polymerase chain reaction or a 4-fold rise in hemagglutinin titers. Effectiveness of the surgical mask was assessed as noninferiority of the surgical mask compared with the N95 respirator. The criterion for noninferiority was met if the lower limit of the 95% confidence interval (CI) for the reduction in incidence (N95 respirator minus surgical group) was greater than –9%.

Results Between September 23, 2008, and December 8, 2008, 478 nurses were assessed for eligibility and 446 nurses were enrolled and randomly assigned the intervention; 225 were allocated to receive surgical masks and 221 to N95 respirators. Influenza infection occurred in 50 nurses (23.6%) in the surgical mask group and in 48 (22.9%) in the N95 respirator group (absolute risk difference, –0.73%; 95% CI, –8.8% to 7.3%; $P = .86$), the lower confidence limit being inside the noninferiority limit of –9%.

Conclusion Among nurses in Ontario tertiary care hospitals, use of a surgical mask compared with an N95 respirator resulted in noninferior rates of laboratory-confirmed influenza.

Trial Registration clinicaltrials.gov Identifier: NCT00756574

JAMA. 2009;302(17):(doi:10.1001/jama.2009.1466) www.jama.com

INFLUENZA CAUSES ANNUAL EPIDEMICS of respiratory illness worldwide and is the most important cause of medically attended acute respiratory illness.[1,2] Moreover, there is increasing concern about the recently declared influenza pandemic due to 2009 influenza A(H1N1) in humans.[3-5]

Transmission of influenza can occur by coughing or sneezing where infectious particles of variable size, ranging from approximately 0.1 to 100 µm, may be inhaled.[6] This range of particles has a yet undefined but possibly important role in transmission. Although data from animal models and human experimental studies suggest that short-range inhalational transmission with small droplet nuclei (<10 µm) can occur,[7-11] the exact nature of transmission of influenza that occurs

See also related article.

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in nonexperimental settings is not well understood.[12] As a consequence, considerable uncertainty exists about the effectiveness of personal respiratory devices against influenza for health care workers.

During a pandemic, reducing transmission of influenza to health care workers may not only help support the health care workforce, but may also prevent influenza transmission to patients. Other personal protective strategies, such as effective vaccines or antiviral drugs, may be limited in availability. Given the likelihood that N95 respirators will be in short supply during a pandemic and unavailable in many countries, understanding the relative effectiveness of personal respiratory protective equipment is important. There are few comparative studies of respiratory protective devices,[13-15] and data comparing the surgical mask with the N95 respirator among health care workers are sparse.

We conducted a randomized trial to compare the surgical mask with the N95 respirator in health care workers. We hypothesized that the surgical mask, which is less expensive and more widely available than the N95 respirator, offers similar protection to the N95 respirator among health care workers at highest risk for exposure to influenza.

METHODS

Participants

We enrolled nurses who worked in emergency departments, medical units, and pediatric units in 8 Ontario tertiary care hospitals, of which 6 were within the greater Toronto area. Six of the 8 hospitals were university-affiliated teaching hospitals (range of bed size, 310-400) and 2 were community hospitals (bed sizes, 256 and 400). Participants were enrolled from a total of 22 units, which included 9 acute medical units, 7 emergency departments, and 6 pediatric units. There were an average of 34 beds (range, 14-60 beds) on the medical units and an average of 27 beds (range, 19-38) on the pediatric units.

Nurses expected to work full-time (defined as >37 hours per week) on study units during the 2008-2009 influenza season were eligible. Nurses had to provide current fit-test certification. Nurses who could not pass a fit test were excluded from the study. The research protocol was approved by the McMaster University research ethics review board. All participants gave written informed consent.

Interventions

Randomization was performed centrally by an independent clinical trials coordinating group such that investigators were blind to the randomization procedure and group assignment and was stratified by center in permuted blocks of 4 participants. It was not possible to conceal the identity of the N95 respirator or the surgical mask since manipulating these devices would interfere with their function. Laboratory personnel conducting hemagglutinin inhibition assays, polymerase chain reaction (PCR), and viral culture for influenza were blinded to allocation. Nurses allocated to the surgical mask group were required to wear the brand of surgical mask already in use at their hospital. Following the severe acute respiratory syndrome (SARS) outbreak in Ontario, use of such a surgical mask was required by the Ministry of Health and Long-Term Care when providing care to or when within 1 m of a patient with febrile respiratory illness, defined as symptoms of a body temperature 38°C or greater and new or worsening cough or shortness of breath.[16] Nurses were instructed in proper placement of the surgical mask according to the manufacturer's recommendations.

Since fit testing is mandatory for nurses in Ontario, the majority of nurses in the study had been fit tested prior to enrollment; additional fit testing was conducted for nurses who had not been fit tested in 2008. Using a standard protocol, a technician showed the participant how to position the respirator and fasten the strap and determine whether it provided an acceptable fit. The nurse was asked to wear the most comfortable mask for at least 5 minutes to assess fit. Adequacy of the respiratory fit was assessed using standard criteria, including chin placement, adequate strap tension, appropriate respirator size, fit across nose bridge, tendency of respirator to slip, and position of mask on face and cheeks. The nurse then conducted a user seal check.[17] Nurses had a qualitative fit testing using the saccharin or Bitrex protocol.[17]

Nurses were asked to begin using the surgical mask or N95 respirator when caring for patients with febrile respiratory illness at the beginning of the influenza season, which was defined as 2 or more consecutive isolations of influenza per week in each study region. Nurses wore gloves and gowns when entering the room of a patient with febrile respiratory illness, which was routine practice. For aerosol-generating procedures (such as intubation or bronchoscopy), as long as tuberculosis was not suspected, nurses continued to use the respiratory device they were assigned to.

We had planned to stop the study at the end of influenza season. However, because of the 2009 influenza A(H1N1) pandemic, the study was stopped on April 23, 2009, when the Ontario Ministry of Health and Long-Term Care recommended N95 respirators for all health care workers taking care of patients with febrile respiratory illness.

Follow-up

All participants were assessed for signs and symptoms of influenza twice weekly using Web-based questionnaires. Response to the questionnaire was monitored centrally and participants who failed to provide a response were contacted and asked to complete the questionnaire. If a new symptom was reported, the study nurse was notified and a flocked nasal specimen (Copan Italia, Brescia, Italy) was obtained by the participants. They were trained to insert the swab into the left or right nostril and rotate the swab at least 3 times and to conduct self-swabbing if

any of 1 of the following symptoms or signs were present: fever (temperature ≥38°C), cough, nasal congestion, sore throat, headache, sinus problems, muscle aches, fatigue, earache, ear infection, or chills. We also provided participants with tympanic thermometers. To assess household exposures between study groups, we asked participants whether household members (spouses, roommates, or children) had experienced influenza-like illness over the study period.

Outcomes

The primary outcome of this study was laboratory-confirmed influenza. This was defined by either the detection of viral RNA using reverse-transcriptase (RT) PCR from nasopharyngeal and flocked nasal specimens or at least a 4-fold rise in serum antibodies to circulating influenza strain antigens. All nasopharyngeal or nasal specimens were tested for influenza and other respiratory viruses with the xTAG Respiratory Virus Panel test (Luminex Molecular Diagnostics, Toronto, Ontario, Canada).[18] This multiplex PCR assay detects influenza A virus subtypes H1 (seasonal), H3, and H5 as well as the majority of other viruses that cause respiratory illness in humans.

Blood specimens for serology were obtained prior to enrollment and at the end of the follow-up period. Serological infection was defined by detection of 4-fold or greater increase in influenza-specific hemagglutinin inhibition assay titer between baseline and convalescent serum samples using guinea pig erythrocytes and the antigens circulating A/Brisbane/59/2007(H1N1)-like virus; A/Brisbane/10/2007(H3N2)-like virus; B/Florida/4/2006-like virus; and A/TN/1560/09(H1N1), the circulating pandemic influenza virus. For A/Brisbane/59/2007(H1N1)-like virus, A/Brisbane/10/2007(H3N2)-like virus, and B/Florida/4/2006-like virus, we restricted serological criteria of infection to nurses who did not receive the trivalent 2008-2009 influenza vaccine to reduce misclassification due to vaccine response.

Secondary outcomes included detection of the following noninfluenza viruses by PCR: parainfluenza virus types 1, 2, 3, and 4; respiratory syncytial virus types A and B; adenovirus; metapneumovirus; rhinovirus-enterovirus; and coronaviruses OC43, 229E, SARS, NL63, and HKU1. Influenza-like illness was defined as the presence of cough and fever (temperature ≥38°C).[19] Work-related absenteeism and physician visits for respiratory illness were also assessed.

Audits

To assess compliance of participants with the assigned mask or N95 respirator, we conducted audits during what we anticipated was peak influenza period, from March 11 to April 3, 2009. Medical and pediatric hospital study units at all centers with nurses participating in the study were contacted by telephone daily by a research assistant to assess whether there were patients admitted to the unit in droplet precautions for influenza or febrile respiratory illness. If there were such cases and if the primary nurse for the patient was enrolled in our study, a trained auditor was sent to the unit to observe for compliance. The auditor was instructed to stand a short distance from the patient isolation room to remain inconspicuous but within distance to accurately record the audit. Auditors were asked to remain on the unit until they recorded the type of protective equipment worn by the participant prior to the participant entering the isolation room.

To maintain patient confidentiality and to remain anonymous to the study participant, no audits were conducted within the patient's room. Once an audit was conducted, the session was completed. Audits were conducted both on weekdays and on weekends during day and evening shifts. Assessment of hand hygiene was not conducted.

Statistical Analysis

The effectiveness of the surgical mask was assessed through a noninferiority analysis relative to the N95 respirator.[20] For the primary analysis, the difference in the incidence of laboratory-confirmed influenza between the N95 respirator group and surgical mask group was estimated and the corresponding 2-sided 95% confidence interval (CI) was calculated. We used the Fisher exact test to assess statistical significance in contingency tables having expected cell frequencies less than 5. Noninferiority to the N95 respirator was achieved if the lower limit of the 95% CI for the reduction in incidence (N95 respirator minus surgical group) was greater than the prespecified noninferiority limit of –9%. Assuming an event rate of 20% in controls, this limit was selected on a clinical basis considering that laboratory-confirmed influenza would include asymptomatic cases in addition to symptomatic cases of influenza. Infection detected by serology can account for up to 75% of cases of laboratory-confirmed influenza where febrile illness is not present.[21]

Since we did not anticipate severe outcomes (eg, mortality) in the study sample, we used a similar approach for influenza-like illness, work-related absenteeism, and physician visits for respiratory illness. All participants who had follow-up data collected (ie, had not withdrawn prior to any follow-up after they had been randomized) were included in the analysis. Since intention-to-treat analyses in noninferiority trials may be biased toward finding no difference, we also conducted an analysis of our primary outcome using only data from participants with complete follow-up.[22]

To avoid lack of independence associated with counting multiple outcomes, each specific outcome in a participant was only counted once. With a power of 90% and a 2-sided type-I error rate of 5%, the required sample would be 191 participants in each group for a noninferiority test assuming an absolute risk reduction of 12% in the N95 respirator group compared with the surgical mask. If the absolute reduction was assumed to be 10%, a statistical power of 80% would be maintained. The absolute risk reductions selected

were based on consensus by clinician investigators. Assuming a 10% dropout rate, we estimated that a total of 420 participants would be needed. SAS version 9.1.3 (SAS Institute, Cary, North Carolina) was used to conduct the analyses.

RESULTS

Between September 23, 2008, and December 8, 2008, 478 nurses were assessed for eligibility and 446 participants from 8 centers in Ontario were enrolled. They were then randomly assigned the intervention, 225 to the surgical mask and 221 to the N95 respirator (FIGURE). The mean age of participants was 36.2 years, 94% of them were female, and study groups were well balanced in terms of demographics (TABLE 1). Vaccination status was similar: 68 participants (30.2%) in the surgical mask group and 62 (28.1%) in the N95 respirator group had received 2008-2009 trivalent inactivated influenza vaccine.

Figure. Flow Diagram for Trial of Surgical Mask vs N95 Respirator

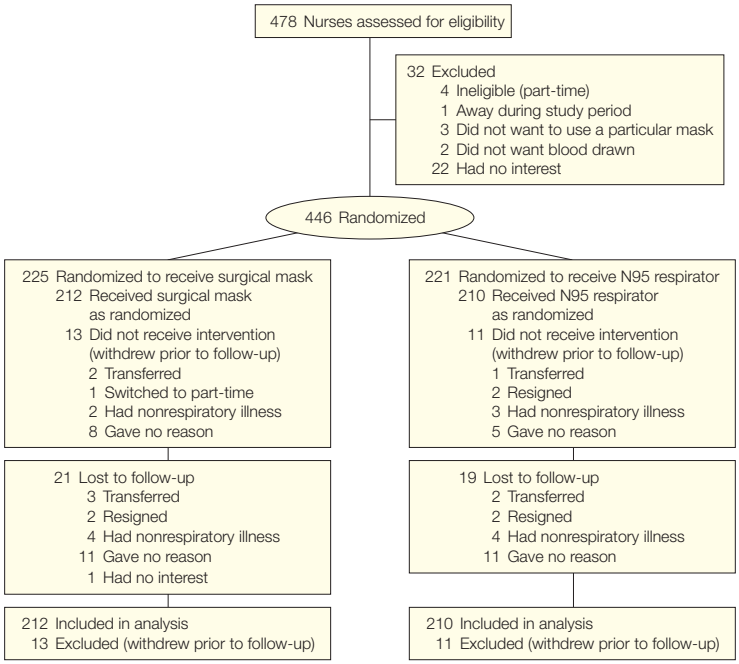

Table 1. Characteristics of 446 Nurse Participants in the Surgical Mask and N95 Respirator Groups

Characteristic	No. (%)	
	Surgical Mask (n = 225)	N95 Respirator (n = 221)
Age, mean (SD) [range], y	36.5 (10.6) [21-62]	35.8 (10.6) [21-60]
Female sex	212 (94.2)	208 (94.1)
Vaccinated against influenza	68 (30.2)	62 (28.1)
≥1 Coexisting conditions	22 (9.8)	26 (11.8)
Asthma	10 (4.4)	12 (5.4)
Diabetes	3 (1.3)	6 (2.7)
Metabolic	2 (1.0)	4 (1.8)
Immunocompromised[a]	3 (1.3)	3 (1.3)
Pregnancy	5 (2.2)	2 (0.9)
Other[b]	6 (2.7)	3 (1.3)
Distribution by hospital unit		
Medical	55 (24.4)	52 (23.5)
Pediatric	58 (26.2)	62 (28.1)
Emergency	112 (49.8)	107 (48.4)

[a] Immunosuppressive medications for transplantation (n=1), rheumatoid arthritis (n=3), uveitis (n=1), and Crohn disease (n=1).
[b] Includes chronic renal failure (n=1), coronary artery disease (n=1), liver disease (n=2), seizures/brain disorder (n=2), and connective tissue disease (n=4).

Follow-up began January 12, 2009, and ended April 23, 2009. Mean (SD) duration of follow-up was similar between groups: 97.9 (16.1) days in the surgical group and 97.2 (18.0) days in the N95 respirator group. There were 24 participants who withdrew from the study with no follow-up—13 in the surgical mask group and 11 in the N95 respirator group—because of resignation or transfer (n=5), working part-time (n=1), no response (n=13), or illness (n=5) (Figure). None of the health care workers withdrew because of respiratory illness. Of the resulting 422 (all of whom were in the analysis), follow-up was complete in 386 (91.4%), and 403 (95.5%) had acute and convalescent sera collected. There were 223 nasal specimens obtained (115 in the surgical mask group and 108 in the N95 respirator group).

Laboratory-confirmed influenza (by RT-PCR or ≥4-fold rise in serum titers) occurred in 50 nurses (23.6%) in the surgical mask group and in 48 (22.9%) in the N95 respirator group (absolute risk difference, –0.73%; 95% CI, –8.8% to 7.3%; *P*=.86), indicating noninferiority of the surgical mask (TABLE 2). The diagnosis of influenza was made by RT-PCR in 6 nurses (2.8%) in the surgical mask group (5 influenza A and 1 influenza B) and 4 (1.8%) in the N95 respirator group (1 influenza A and 3 influenza B) (absolute risk difference, –0.93%; 95% CI, –3.82% to 1.97%; *P*=.75). Four of the influenza A cases detected by PCR were H1 (all in the surgical mask group). The serology results are summarized in Table 2. Notably, 8.0% in the surgical mask group and 11.9% in the N95 respirator group had a

4-fold or greater rise in serum titers to A/TN/1560/09(H1N1), the circulating pandemic swine influenza strain. Noninferiority was demonstrated between the surgical mask group and the N95 respirator group for 2009 influenza A(H1N1) (absolute risk difference, 3.89%; 95% CI, –1.82% to 9.59%; $P=.18$).

When the analysis was conducted using only the data from participants with complete follow-up visits, laboratory-confirmed influenza (by RT-PCR or ≥4-fold rise in serum titers) occurred in 66 nurses (33.9%) in the surgical mask group and in 72 (37.7%) in the N95 respirator group (absolute risk difference, 3.85%; 95% CI, –5.71% to 13.41%; $P=.43$), indicating noninferiority.

No adenoviruses; no respiratory syncytial virus type A; and no parainfluenza 1, 2, and 4 viruses were detected by PCR. There were no significant differences between the surgical mask and N95 respirator groups in respiratory syncytial virus type B, metapneumovirus, parainfluenza 3, rhinovirus-enterovirus, or coronoviruses. The lower CIs for the differences were greater than –9%, meeting our criteria for noninferiority (TABLE 3). All 52 (100%) of those having infection with a respiratory virus other than influenza had 1 or more symptoms, but they did not meet the influenza-like illness definition.

Nine nurses (4.2%) in the surgical mask group and 2 nurses (1.0%) in the N95 respirator group met our criteria for influenza-like illness (absolute risk difference, –3.29%; 95% CI, –6.31% to 0.28%; $P=.06$) (TABLE 4). All 11 had laboratory-confirmed influenza. A significantly greater number of nurses in the surgical mask group (12, or 5.66%) reported fever compared with the N95 respirator group (2, or 0.9%; $P=.007$). There was no significant difference in nurses who reported cough, nasal congestion, headache, sore throat, myalgia, fatigue, earache, or ear infection. Of the 44 nurses in each group who had influenza diagnosed by serology, 29 (65.9%) in the surgical mask group and 31 (70.5%) in the N95 respirator group had no symptoms.

There were 13 physician visits (6.1%) for respiratory illness among those in the surgical mask group compared with 13 (6.2%) in the N95 respirator group (absolute risk difference, –0.06%; 95% CI, –4.53% to 4.65%; $P=.98$). Forty-two participants (19.8%) in the surgical mask group reported an episode of work-related absenteeism compared with 39 (18.6%) in the N95 respiratory group (absolute risk difference, –1.24%; 95% CI, –8.75% to 6.27%; $P=.75$) (Table 4). There were no episodes of lower respiratory tract infec-

Table 2. Comparison of Laboratory-Confirmed Influenza Between the Surgical Mask and N95 Respirator Groups

	No. (%)			
	Surgical Mask (n = 212)	N95 Respirator (n = 210)	Absolute Risk Difference, % (95% CI)	*P* Value
Laboratory-confirmed influenza[a]	50 (23.6)	48 (22.9)	–0.73 (–8.8 to 7.3)	.86
RT-PCR influenza A	5 (2.4)	1 (0.5)	–1.88 (–4.13 to 0.36)	.22
RT-PCR influenza B	1 (0.5)	3 (1.4)	0.96 (–0.89 to 2.81)	.37
≥4-Fold rise in serum titers A/Brisbane/59/2007 (H1N1)[b]	25 (11.8)	21 (10)	–1.79 (–7.73 to 4.15)	.55
≥4-Fold rise in serum titers A/Brisbane/10/2007 (H3N2)[b]	42 (19.8)	49 (23.3)	3.52 (–4.32 to 11.36)	.38
≥4-Fold rise in serum titers B/Florida/4/2006[b]	15 (7.1)	19 (9.0)	2.0 (–3.0 to 7.17)	.46
≥4-Fold rise in serum titers A/TN/1560/09 (H1N1)[b]	17 (8.0)	25 (11.9)	3.89 (–1.82 to 9.59)	.18

Abbreviations: CI, confidence interval; RT-PCR, reverse-transcriptase polymerase chain reaction.
[a] Influenza detected by 1 or more of the following: RT-PCR A, RT-PCR B, and ≥4-fold rise in serum titers to A/Brisbane/59/2007(H1N1), A/Brisbane/10/2007(H3N2), and B/Florida/4/2006. Serology includes only nonvaccinated nurses.
[b] Includes both vaccinated and nonvaccinated nurses. Two hundred ninety-four nurses were not vaccinated (147 in each group).

Table 3. Comparison of RT-PCR Results for Other Respiratory Viruses Between the Surgical Mask and N95 Respirator Groups

	No. (%)			
	Surgical Mask (n = 212)	N95 Respirator (n = 210)	Absolute Risk Difference, % (95% CI)	*P* Value
Respiratory syncytial virus[a]	2 (0.9)	1 (0.5)	–0.47 (–2.07 to 1.13)	>.99
Metapneumovirus	4 (1.9)	3 (1.4)	–0.46 (–1.98 to 2.89)	>.99
Parainfluenza virus[b]	1 (0.5)	2 (1.0)	0.48 (–1.12 to 2.09)	.62
Rhinovirus-enterovirus	8 (3.8)	10 (4.8)	0.99 (–2.87 to 4.85)	.62
Coronavirus[c]	9 (4.3)	12 (5.7)	1.47 (–2.68 to 5.62)	.49
Total[d]	20 (9.4)	22 (10.5)	1.04 (–4.67 to 6.76)	.72

Abbreviations: CI, confidence interval; RT-PCR, reverse-transcriptase polymerase chain reaction.
[a] Refers to respiratory syncytial virus type B only because no type A was detected.
[b] Refers to parainfluenza 3 only because no parainfluenza 1, 2, or 4 was detected.
[c] Refers to coronaviruses OC43, 229E, NL63, and HKU1.
[d] Totals are less than sums because more than 1 virus was detected in some participants.

Table 4. Clinical Outcomes Between the Surgical Mask and N95 Respirator Groups

	No. (%)			
	Surgical Mask (n = 212)	N95 Respirator (n = 210)	Absolute Risk Difference, % (95% CI)	*P* Value
Physician visits for respiratory illness	13 (6.1)	13 (6.2)	–0.06 (–4.53 to 4.65)	.98
Influenza-like illness[a]	9 (4.2)	2 (1.0)	–3.29 (–6.31 to 0.28)	.06
Work-related absenteeism	42 (19.8)	39 (18.6)	–1.24 (–8.75 to 6.27)	.75

Abbreviation: CI, confidence interval.
[a] Influenza-like illness was defined as the presence of both cough and temperature 38°C or greater.

tion among participants. There were no adverse events reported by participants.

Fifty-five participants (25.9%) in the surgical mask group vs 47 (22.4%) in the N95 respirator group reported a spouse or roommate with influenza-like illness ($P=.39$). Forty-eight participants (22.6%) in the surgical mask group vs 43 (20.5%) in the N95 respirator group reported a child with influenza-like illness ($P=.59$).

Over the 2-week audit period, there were 18 episodes of patients admitted to units in droplet precautions for influenza or febrile respiratory illness where the nurse providing care for the patient had been enrolled in our study. The results of the audit demonstrated that all 11 participants (100%) allocated to surgical masks and 6 of 7 participants (85.7%) allocated to N95 respirators were wearing the device to which they had been assigned.

COMMENT

Our data show that the incidence of laboratory-confirmed influenza was similar in nurses wearing the surgical mask and those wearing the N95 respirator. Surgical masks had an estimated efficacy within 1% of N95 respirators. Based on the prespecified definition, the lower CI for the difference in effectiveness of the surgical mask and N95 mask was within –9% and the statistical criterion of noninferiority was met. That is, surgical masks appeared to be no worse, within a prespecified margin, than N95 respirators in preventing influenza.

Transmission by small droplet spread would be compatible with greater protection with the N95 mask compared with the surgical mask where efficiency estimates range from 2% to 92% for particles smaller than 20 µm in diameter.[23-28] The fact that attack rates were similar may suggest that small aerosols did not dominate transmission.

One frequently cited concern about the surgical mask is its inability to obtain an appropriate seal compared with the N95 respirator.[29] Based on the results of this trial, this concern does not seem to be associated with an increased rate of infection of influenza or other respiratory viruses.

Influenza attack rates among health care workers in non-outbreak settings are sparse. Our data provide estimates of an attack rate (23%) in a largely unvaccinated cohort of nurses followed closely during a period of relatively mild influenza-like illness and into the beginning of what is now considered a pandemic period. Given that serology captures exposure over the entire season and that nurses have repeated exposures, this rate of infection was not unexpected. Our serological data in unvaccinated nurses were 20% for H3N2, 10% for H1N1, and 8% for influenza B. In a community-based study, age-specific rates of infection for those aged 30 to 39 years by serology was 16% for H3N2, approximately 5% for H1N1, and 5% for influenza B.[21] It is for this reason that the number of participants with influenza-like illness, defined by fever and cough alone,[19] were relatively few compared with the number with laboratory-confirmed influenza. Given that there was no difference in laboratory-confirmed influenza between study groups, the higher proportion of nurses in the surgical mask group with influenza-like illness, although not statistically significant, was unexpected.

The results of seroconversion to 2009 influenza A(H1N1) (10%) was unexpected given that the convalescent specimens were obtained from April 23 to May 15, 2009. This attack rate may suggest that 2009 influenza A(H1N1) was circulating in Ontario before April 2009. An alternative explanation for this high rate of seroconversion may be cross-reaction due to exposure to seasonal H1N1.

Strengths of this study include individual-level randomization, comprehensive laboratory-confirmed outcome assessment with PCR and serological evaluation, follow-up over an entire influenza season, and excellent participant follow-up.

There are a number of limitations of this study. Compliance with the intervention could not be assessed for all participants. Only 1 room entry was recorded per observation and the auditor did not enter the isolation room to assess whether the participant removed the respirator protection. Audits were only conducted on medical and pediatric units, not in the emergency department. Had there been poor compliance with the N95 respirator, this could have biased the study toward noninferiority. However, the results from our audited sample suggest excellent adherence. This is in keeping with the fact that all hospitals in the study were in Ontario, which was affected by the SARS outbreak and where use of personal protective equipment is mandated and audited by the Ontario Ministry of Labour.

We acknowledge that our protocol did not account for the effect of indirect contact because hand hygiene and use of gloves and gowns were not monitored. An imbalance in hand hygiene between study groups, with worse adherence in the N95 group, would have biased the study toward noninferiority. However, individual-level randomization and stratified randomization within hospitals would help balance any differences in adherence to hand hygiene between study groups. Because the use of gloves and gowns when entering the room of a patient with febrile respiratory illness was standard practice in our study hospitals, variability of use would likely have been minimal.

It is also impossible to determine whether participants acquired influenza due to hospital or community exposure. However, our data on household exposure suggest that such exposures were balanced between intervention groups. We acknowledge that not surveying participants' coworkers about influenza-like illness was a limitation. Since we did not collect information on droplet isolation precautions, a greater exposure of N95 respirator nurses vs surgical mask nurses to patients on droplet precautions would

have biased the study toward noninferiority. However, the fact that the nurses were well balanced on each ward and in the number of specimens obtained on each unit would minimize the chance of such differential exposure having occurred.

The major implication of this study is that protection with a surgical mask against influenza appears to be similar to the N95 respirator, meeting criteria for noninferiority. Our findings apply to routine care in the health care setting. They should not be generalized to settings where there is a high risk for aerosolization, such as intubation or bronchoscopy, where use of an N95 respirator would be prudent. In routine health care settings, particularly where the availability of N95 respirators is limited, surgical masks appear to be noninferior to N95 respirators for protecting health care workers against influenza.

Published Online: October 1, 2009 (doi:10.1001/jama.2009.1466).
Author Contributions: Dr Loeb had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
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Obtained funding: Loeb, Walter.
Administrative, technical, or material support: Dafoe, John, Sarabia, Smieja, Earn, Chong, Webb.
Study supervision: Loeb, Mahony, Webby.
Financial Disclosures: None reported.
Funding/Support: This study was supported by the Public Health Agency of Canada.
Role of the Sponsor: The funding organization had no role in the design and conduct of the study; in the collection, analysis, and interpretation of the data; or in the preparation, review, or approval of the manuscript.

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CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR PUBLIC HEALTH

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Janie Miller
Secretary

MEMORANDUM

To: All Local Health Departments; All Public and Environmental Health Directors and Staff, Nursing and EPI staff;
And School Superintendents

From: Guy F. Delius, R.S., Director,
Division of Public Health Protection & Safety

Date: September 1, 2009

Subject: Hand Sanitizer in Schools.

The Following information relates to use of hand sanitizers in Kentucky schools. In March 2009, this office has issued guidance for use of "Toxic Items in Schools", which included hand sanitizers. This guidance was released due to the risks associated with the use or abuse of some toxic items, including hand sanitizers. With the occurrence of H1N1 this year, and the heightened need of "clean hands", our guidance is being revised, to allow a more liberal use of hand sanitizers during this event. The use of hand sanitizers can be an effective tool in maintaining clean hands and minimizing the spread of disease, when used in conjunction with proper hand washing.

Proper hand washing using warm water, soap and sanitary towels is the best method to clean hands and combat illness. According to the CDC, **"hand washing is the single most important means of preventing the spread of infection."** Washing ones hands with warm water and soap vigorously for 15-20 seconds and drying them with a paper towel or hand dryer is preferred. Teachers and children should take regular breaks to wash their hands and bathrooms should be checked often to ensure that soap and paper towels are available at all times. Students and faculty should wash hands when hands are visibly soiled; before eating; after using the bathroom; after handling animals or their waste; after recess; after sneezing, etc.

The use of hand sanitizers can be an effective alternative to maintaining clean hands and minimizing the spread of disease, when soap and water are not readily available. During the Pandemic our guidance will temporarily allow the use of hand sanitizers between times of routine hand washing, for grades 4-12. Hand sanitizers are best used with supervision, but may be used by students in these grades if the school system permits. Care should be taken to follow all instructions and warnings on the product labels. Along with the benefits of hand sanitizers there is a risk of abuse or misuse of these products so use is recommended in accordance with manufacturer's requirements.

At this time the use of hand sanitizers for children in K-3rd grade or children that may have physical and developmental disabilities should be practiced with supervised use only, and the products should be locked away from these children when not in use.

If you have any questions regarding the use of hand sanitizers, please contact your local health department environmental health professional office or Ms. Vonia Grabeel at the Kentucky Department for Public Health's Environmental Management Branch at (502) 564-7398.

Useful URL's for Novel H1N1 Influenza Information as of 10/1/09

General/Comprehensive Influenza Websites

Kentucky Health Alerts Website
healthalerts.ky.gov

CDC novel H1N1 Influenza Website
http://www.cdc.gov/h1n1flu/ *(English)*
http://www.cdc.gov/h1n1flu/espanol/ *(Spanish)*

U.S. Department of Health and Human Services Influenza Website
http://www.flu.gov *(English)*
http://espanol.pandemicflu.gov/pandemicflu/enes/24/_www_flu_gov/ *(Spanish)*

World Health Organization H1N1 Website
http://www.who.int/csr/disease/swineflu/en/index.html

FEMA General Preparedness Website
http://www.ready.gov/ *(General preparedness)*
http://www.ready.gov/kids/home.html *(Great kids website)*

Stopping Germs at Home, Work and School
http://www.cdc.gov/germstopper/home_work_school.htm
http://www.cdc.gov/flu/protect/habits.htm

H1N1 Websites for Health Professionals

Kentucky Health Alerts Novel H1N1 Health Professionals Website
http://healthalerts.ky.gov/swineflu/healthpros.htm

HHS Influenza Planning Website for Health Care
http://www.flu.gov/plan/healthcare/index.html

Novel H1N1 Influenza: Resources for Clinicians
http://www.cdc.gov/h1n1flu/clinicians/

Specimen Collection, Processing, and Testing for Patients with Suspected Novel Influenza A (H1N1) Virus Infection
http://www.cdc.gov/h1n1flu/specimencollection.htm

Infection Control for Novel H1N1 Influenza Virus in a Healthcare Setting
http://www.cdc.gov/h1n1flu/guidelines_infection_control.htm

Recommendations for Facemask and Respirator Use to Reduce Novel Influenza A (H1N1) Virus Transmission
http://www.cdc.gov/h1n1flu/masks.htm

Considerations for Clinicians Regarding HIV-Infected Adults and Adolescents
http://www.cdc.gov/h1n1flu/guidance_HIV.htm

H1N1 Websites for Businesses

Common Workplace Questions
http://www.pandemicflu.gov/faq/workplace_questions/index.html

Guidance for Businesses and Employers for the 2009–2010 Influenza Season
http://www.pandemicflu.gov/plan/workplaceplanning/guidance.html
http://www.cdc.gov/h1n1flu/business/

Preparing for the Flu: A Communication Toolkit for Businesses and Employers
http://www.pandemicflu.gov/plan/workplaceplanning/toolkit.html
CDC H1N1 Flu Resources for Businesses and Employers
http://www.cdc.gov/h1n1flu/business/

NIOSH - Occupational Health Issues Associated with H1N1 Influenza Virus
http://www.cdc.gov/niosh/topics/h1n1flu/

H1N1 Websites for Schools

H1N1 Flu (Swine Flu): Resources for Child Care and Early Childhood Programs
http://www.cdc.gov/h1n1flu/childcare/

H1N1 Flu: Resources for Child Care Programs, Schools, Colleges, and Universities (CDC)
http://www.cdc.gov/h1n1flu/schools/

HHS Influenza Planning Website for Schools
http://www.flu.gov/plan/school/index.html

Prevention Strategies for Schools (K-12) during the 2009-2010 School Year
http://www.cdc.gov/h1n1flu/schools/schoolguidance.htm

Preparing for the Flu: A Communication Toolkit for Schools (CDC)
http://www.cdc.gov/h1n1flu/schools/toolkit/

CDC Communication Toolkit for Institutions of Higher Education
http://www.cdc.gov/h1n1flu/institutions/toolkit/

Interim CDC Guidance on Day and Residential Camps in Response to Human Infections with the Novel Influenza A (H1N1) Virus
http://www.cdc.gov/h1n1flu/camp.htm

H1N1 Websites for Public and Families

H1N1 Flu General Information
http://www.cdc.gov/h1n1flu/general_info.htm

HHS Influenza Planning Website for Families
http://www.flu.gov/plan/individual/index.html

HHS Influenza Planning Website for Communities
http://www.flu.gov/plan/community/index.html

CDC Resources for Parents and Caregivers
http://www.cdc.gov/h1n1flu/parents/

Taking Care of a Sick Person in Your Home
http://www.cdc.gov/h1n1flu/guidance_homecare.htm

H1N1 Websites for Special Groups or Populations

H1N1 Flu Resources for Laboratories
http://www.cdc.gov/h1n1flu/lab/

CDC Resources for Pregnant Women
http://www.cdc.gov/h1n1flu/pregnancy/

What Pregnant Women Should Know About H1N1 Virus
http://www.cdc.gov/h1n1flu/guidance/pregnant.htm

Novel H1N1 Flu and Travel
http://wwwn.cdc.gov/travel/content/novel-h1n1-flu.aspx

What Adults with HIV Infection Should Know About the Novel H1N1 Flu
http://www.cdc.gov/h1n1flu/hiv_flu.htm

Novel H1N1 Influenza Website for the Deaf
http://www.deafmd.org/pub/Swine-Flu-Influenza-A-H1N1/Public-Service-Announcement

People who have Close Contact with Pigs in Non-commercial Settings
http://www.cdc.gov/H1N1flu/guidelines_pig_workers.htm

Health Recommendations for Relief Workers Responding to Disasters
http://wwwn.cdc.gov/travel/content/relief-workers.aspx

H1N1 FAQ for LHDs

Kentucky Department for Public Health
Frequently Asked Questions on Novel H1N1

September 30, 2009

Table of Contents

Note: Some questions that may "cross" categories, if you don't see your question in one section it may be in another. Please send H1N1 questions and comments to the DOC inbox at: chfsdphdoc@ky.gov . It is listed on the Global as CHFS DPH DOC

What's new today

- **Pediatric Prescription of Oseltamivir (Tamiflu) for H1N1 Influenza Treatment**

The attached guidance gives crucial information on replacement of pediatric suspension of pre-packaged Tamiflu suspension in case of predicted shortages. Please distribute to your constituencies as appropriate.

Pediatric Prescription of Oseltamivir (Tamifl

- **Fact Sheet for Older Adults**

This fact sheet for older adults regarding vaccine has been shared by the Dept. for Aging and Independent Living with the aging network in Kentucky. Other groups that work with older adults have also been given this information. Also attached is a contact list for the Area Agencies on Aging and Independent Living (AAAIL) just in case LHD's want to contact them about outreach to this population. AAAIL Directors were alerted by Commissioner Anderson that LHD's may be contacting them.

vaccine recs for people 50andolder-0

ADD Map.ppt

- **Immunizations by pharmacists**

Brad Hall, executive Director and CEO of the Kentucky Pharmacists Association, provided this guidance regarding KRS 315.010 (19). This statute describes the circumstances under which a Kentucky pharmacist can immunize a specific patient. In accordance with KRS 315.010 (19), pharmacists can immunize pursuant to a protocol for individuals 18 years of age and older. For patients younger than 18 years of age, a pharmacist can immunize pursuant to a prescription from an authorized prescriber for a specific patient.

On a related issue, a few local health departments have received calls from pharmacies that state their agency uses "certified vaccine providers". Per Brad Hall, the American Pharmacists Association offers certification programs to train pharmacists who administer immunizations. However, he stated that Kentucky law does not mandate additional training for pharmacists who immunize individuals other than the requirement to be a licensed pharmacist (KRS 315.010 (19)).


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.pdf

New from CDC

Antiviral guidance for obstetric care providers
http://www.cdc.gov/h1n1flu/pregnancy/antiviral_messages.htm

Information for Pharmacists
http://www.cdc.gov/H1N1flu/pharmacist/pharmacist_info.htm

This document provides 1.) background information on influenza activity to date and how pharmacists may be affected this season, 2.) an update on antiviral drug supplies, 3.) information about compounding an oral suspension from Tamiflu® 75mg capsules and 4.) information about the oral dosing dispenser provided with certain formulations of Tamiflu® oral suspension.

Updated Interim **Recommendations for the Use of Antiviral Medications** in the Treatment and Prevention of Influenza for the 2009-2010 Season was issued earlier this week. http://www.cdc.gov/h1n1flu/recommendations.htm

School-Located Vaccination
There are sections in a new CDC School-Located Vaccination (SLV) guidance document on FERPA and HIPPA:

http://www.cdc.gov/h1n1flu/vaccination/slv/planners.htm#ferpa
<http://www.cdc.gov/h1n1flu/vaccination/slv/planners.htm#ferpa>

http://www.cdc.gov/h1n1flu/vaccination/slv/planners.htm#hipaa
<http://www.cdc.gov/h1n1flu/vaccination/slv/planners.htm#hipaa>

Today's Updates

- Flu Mist
- Waiting periods for live virus vaccine
- Thimerosal-free vaccine availability
- Ancillary supply (syringes, needles, and alcohol pads) Kits for vaccination sites
- Provider enrollment questions
- H1N1 vaccine for pregnant women

General

Question: I have been watching Youtube videos that claim that some states will be making the swine flu vaccine mandatory. They also claim that infants and children will be forcefully vaccinated first. I also have been keeping track of the many claims that vaccines are responsible for health problems in some vulnerable populations.

I hope that Kentucky is providing plenty of opportunities for vaccination, but not making it mandatory? I also hope that parents will be given the chance to provide fully informed consent prior to vaccine being given to their children?

> **Answer:** The H1N1 vaccination, when it becomes available, will be voluntary rather than mandatory. As with all vaccines, parents and vaccine recipients will be provided with a Vaccine Information Statement that explains the benefits and risks of the vaccine, prior to vaccination.
>
> For advice about whether you should receive the vaccine, please consult with your medical provider to determine if you have a medical contraindication, are in a high-risk group, etc... (9/9/09)

Question: We have been trying to make sure we are as prepared as we can be to combat the H1N1. Everything I have read talks about alcohol based hand sanitizer. We have a benzalkonium chloride hand sanitizer. What are your thoughts on this product? Is it as effective as the alcohol based?"

> **Answer:** When antimicrobial spectrum against viruses is a concern, 'Benzalkonium chloride hand sanitizer" would **not** be recommended as a good alternative to alcohol-based hand hygiene agents when soap and water handwashing is not available.
>
> Hand-hygiene antiseptic agents have primarily been evaluated for effectiveness in healthcare settings. See the appendix, http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5116a2.htm, to the CDC "**Guideline for Hand Hygiene in Healthcare Settings - 2002**", http://www.cdc.gov/handhygiene/ for additional information..
>
> Quaternary ammonium compounds (like benzalkonium chloride) have 1+ activity against viruses compared to 3+ activity for alcohol-based products. Quaternary ammonium compounds have the additional disadvantage of a "slow" speed of action compared to a "fast" speed of action in the alcohol-based products.
>
> Be cautioned that alcohol based sanitizers are not a substitute for proper handwashing. It is to be used in conjunction with proper handwashing or in the case of no water.

Question: Who needs to be tested for H1N1?

Answer: Not everyone with influenza-like symptoms needs to be tested, since public health recommendations for novel H1N1 and seasonal influenza are much the same. Individuals who are ill enough that their condition warrants hospitalization, pregnant women, and individuals in institutionalized settings should be tested. Samples from patients who meet these criteria can be sent to the Division of Laboratory services. If clinicians feel patients that do not meet these criteria should be tested, specimens can be sent to a commercial reference lab for testing. Many commercial clinical labs can now test for H1N1.

Seasonal Flu

Question: When should seasonal influenza vaccine be given**?**

Answer: In general, health-care providers should begin offering vaccination soon after vaccine becomes available and if possible by October. To avoid missed opportunities for vaccination, providers should offer vaccination during routine health-care visits or during hospitalizations whenever vaccine is available. The potential for addition of a novel influenza A (H1N1) vaccine program to the current burden on vaccination programs and providers underscores the need for careful planning of seasonal vaccination programs. Beginning use of seasonal vaccine as soon as available, including in September or earlier, might reduce the overlap of seasonal and novel influenza vaccination efforts.*",*
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5808a1.htm?s_cid=rr5808a1_e

Question: We have started with the push of seasonal flu vaccine and I have been getting questions, since it is early in getting the vaccine will there be a need to repeat the vaccine in Jan.?

Answer: A second seasonal flu vaccination is NOT indicated, except for those under 9 years who are receiving their first seasonal flu vaccination. Vaccination in Sept should provide immunity throughout the traditional flu season, i.e., on into Jan, Feb and Mar.

LHD Attachments 2009-2010 (3)....

Influenza Revaccination of Elderly Travelers: Antibody Response to Single Influenza Vaccination and Revaccination at 12 Weeks. Jane A. Buxton, Danuta M. Skowronski, Helen Ng, Steve A. Marion, Yan Li, Arlene King and James Hockin. *The Journal of Infectious Diseases*, Vol. 184, No. 2 (Jul. 15, 2001), pp. 188-191. **http://www.jstor.org/pss/30137164** (9/11/09)

Question: Are there any changes in recommendations for pneumococcal vaccines?

Answer: No, the ACIP recommends that persons recommended for pneumococcal vaccine receive it in light of the potential for increased risk of pneumococcal disease associated with influenza. There are at present no recommendations to give pneumococcal vaccine to groups for whom it is not currently recommended. ACIP will revisit this question as epidemiologic data from the Southern hemisphere influenza season and from the U.S. become available. (9/11/09)

Question: Can the seasonal flu vaccine and the novel H1N1 vaccine be administered at the same time?

Answer: Simultaneous administration of inactivated vaccines against seasonal and novel influenza A (H1N1) viruses is permissible if different anatomic sites are used. However, simultaneous administration of live, attenuated vaccines against seasonal and novel influenza A (H1N1) virus is not recommended.

Normally 2 live vaccines can either be given simultaneously or separated by 4 weeks, however; MMWR, August 21, 2009 / Vol. 58,
"Use of Influenza A (H1N1) 2009 Monovalent Vaccine Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009", page 6 states:

Current studies indicate the risk for infection among persons aged >65 years is less than the risk for persons in younger age groups. Expanding vaccination recommendations to include adults aged >65 years is recommended only after assessment of vaccine availability and demand at the local level. Once demand for vaccine among younger age groups is being met, vaccination should be expanded to all persons aged >65 years. This recommendation might need to be reassessed as new epidemiologic, immunologic, or clinical trial data warrant and in the context of global need for vaccine.

ACIP makes the following additional recommendations about use of influenza A (H1N1) 2009 monovalent vaccine:

- The number of doses of vaccine required for immunization against novel influenza A (H1N1) has not been established. Because vaccine availability is expected to increase over time, vaccine should not be held in reserve for patients who already have received 1 dose but might require a second dose.
    - Simultaneous administration of inactivated vaccines against seasonal and novel influenza A (H1N1) viruses is permissible if different anatomic sites are used. However, simultaneous

administration of live, attenuated vaccines against seasonal and novel influenza A (H1N1) virus is not recommended.

- All persons currently recommended for seasonal influenza vaccine, including those aged >65 years, should receive the seasonal vaccine as soon as it is available. Recommendations for use of the 2009–10 seasonal influenza vaccine have been published previously (12). (9/18/09)

Schools

Note: CDC has altered recommendation for exclusion of ill children and staff from child care. Recommendation was 7 days, but is now 24 hours fever-free, just like K-12 schools: http://www.cdc.gov/h1n1flu/childcare/guidance.htm This document refers to "early childhood programs" which includes center-based and home-based child care programs, Head Start programs, and other early childhood programs providing care for children in group settings. The guidance applies to all early childhood programs, even if they provide services for older children.

We have updated our guidance for the use of hand sanitizers in schools. This updated guidance allows for a more liberal use of sanitizers in light of and during the H1N1 situation. (9/9/09)

DOC090109.pdf

Question: Are there any guidelines for schools or businesses about sharing information with employees or students if they are aware of a confirmed case of someone in their facility?

Answer: Schools and businesses should not share info about confirmed cases, since it's a violation of an individual's protected health information. H1N1 activity is now widespread in KY, so it can be assumed that every community and business is potentially affected. Employees and schoolchildren should practice behaviors that would reduce their risk of illness. The CDC website contains additional information on the Family Educational Rights and Privacy Act (FERPA) which protects the privacy of student education records, including health records, maintained by educational agencies and institutions. http://www.cdc.gov/h1n1flu/vaccination/slv/planners.htm#ferpa

Question: Some of our schools have preschoolers (who are <5yrs), would the same exclusion period apply as CHILDCARE FACILITIES for children less than 5 years of age or because they are in public school system they would have to follow the revised 24 hours exclusion?

Revised Answer: CDC no longer recommends that a longer period should be used in childcare facilities for children less than 5 years of age. Children and caregivers with flu-like illness should remain at home and away from others until at least 24 hours after they are free of fever (100° F [37.8° C] or greater when measured orally), or signs of a fever, without the use of fever-reducing medications. Any pre-school classes within a public school system do not need to follow the 7-day exclusion period. (9/9/09)

Question: Do children in daycare and pre-school need to get both the seasonal and H1N1 flu vaccinations?

Answer: The best way to protect against the flu – seasonal or 2009 H1N1 – is to get vaccinated. The CDC Guidance for Child Care Programs Respond to advises that children less than 5 years of age are at increased risk of complications from influenza (flu); the risk is greater among children less than 2 years old. **Importantly, infants less than 6 months of age represent a particularly vulnerable group because they are too young to receive the seasonal or 2009 H1N1 influenza vaccine; as a result, individuals responsible for caring for these children constitute a high-priority group for early vaccination.** (9/9/09)

Question: The attendance folks at central school office asked if the state (either through Education or DPH) could come up with a standard physician's excuse specific to flu that would allow physicians to quickly provide this required documentation.

Answer: That will be up to the Department of Education, as we in Public Health do not regulate school attendance. However, our suggestion would be that during the pandemic school districts may need to relax attendance policies so that all children/staff that are ill can stay home until they have been 24 hours without a fever. In most cases, schools should take parents' word for this, instead of requiring a doctors' excuse on each child, thus subjecting them to a doctor's visit that might be an opportunity for others to become infected.

Question: How do we protect students with chronic medical conditions prior to the availability of H1N1 vaccine?

Answer: These children's' families and schools should also practice non-medical countermeasures such as handwashing, covering coughs, and staying home when ill. These children are recommended to receive seasonal influenza vaccine as soon as it's available. (9/11/09)

Question: The school district is considering a school-based H1N1 clinic, managed by the LHD. The school district employs several nurses, as does the

tech school. There was concern over how the school-employed nurses would be covered for liability when they are providing a LHD service.

Answer: All vaccinators are supposed to be covered under the federal PREP Act, if they are acting in good faith. However, since Kentucky's constitution is a bit different from other states, we are awaiting a legal opinion from our CHFS legal counsel as to how much protection the PREP is likely to give vaccinators in Kentucky.

Question: Do school and public health nurses have to be fit-tested for N-95 masks?

Answer: Fit-testing for wearing N95 respirators will be required for healthcare personnel, including school nurses, who come into direct contact with patients with influenza virus infections, based upon an Institute of Medicine report that was released yesterday.

"**Healthcare workers who come into direct contact with patients who are infected with the pandemic H1N1 influenza virus or who may be infected should wear N95 respirator masks and not regular surgical masks, a special panel of the Institute of Medicine reported today."** (9/8/09) http://latimesblogs.latimes.com/booster_shots/2009/09/swine-flu-healthcare-workers-should-wear-n95-masks-iom-says.html. The actual reports can be downloaded, http://www.nap.edu/catalog.php?record_id=12748

Question: A school asked if they need to be concerned about a temperature until it is 100 or above. Would they need to send a child home with a temperature in the 99.0 to 99.9 range?

Answer: "Influenza Like Illness (ILI) is defined as fever (temperature of 100°F [37.8°C] or greater) and a cough and/or a sore throat in the absence of a KNOWN cause other than influenza."
http://www.cdc.gov/flu/weekly/fluactivity.htm

Question: I have received several questions from school regarding sanitizer use. What is the guidance regarding sanitizer in classrooms?

Answer: We think it's OK for children to have sanitizers as long as the child is 4th grade or older and school policy permits it. Remember that although hand sanitizer has its place, an old-fashioned scrubbing with soap and water is preferable.

Question: Should the school separate ill students and staff?

Answer: CDC recommends that students and staff who appear to have an influenza-like illness at arrival or become ill during the day be promptly

separated from other students and staff and sent home. Schools should regularly update contact information for parents so that they can be contacted more easily if they need to pick up their ill child. Students and staff who appear to have flu-like illness should be sent to a room separate from others until they can be sent home. CDC recommends that they wear a surgical mask, if possible, and that those who care for ill students and staff wear protective gear such as a mask.

Question: for schools, how long should a sick student or staff member be kept home?

Answer: In the current flu conditions, students and staff with symptoms of flu should stay home for at least 24 hours after they no longer have fever or do not feel feverish, without using fever-reducing drugs. They should stay home even if they are using antiviral drugs.
Sick people should stay at home, except to go to the doctor's office, and should avoid contact with others. Keeping people with a fever at home may reduce the number of people who get infected. Because high temperatures are linked with higher amounts of virus, people with a fever may be more contagious." (For more information, see CDC Recommendations for the Amount of Time Persons with Influenza-Like Illness Should be Away from Others.)

Question: What should schools do for cleaning if they have a H1N1 case?

Answer: School staff should routinely clean areas that students and staff touch often with the cleaners they typically use. Special cleaning with bleach and other non-detergent-based cleaners is not necessary.

Question: There is a general frustration amongst the teachers, principals, nurses and parents present on the lack of actual H1N1 confirmation through testing. There is a suggestion for physicians to test a limited number of children as a way to prove that the outbreak is what the CDC says it is.

Answer: At this stage, seasonal flu and H1N1 flu are being treated the same in terms of public health and school exclusion criteria, so how is knowing whether an influenza outbreak is one or the other going to change patient or public heath management? According to our surveillance, almost all circulating flu in Kentucky at this time is the novel H1N1 strain. Perhaps the only reasons to get confirmatory testing for community outbreaks are a) to feed the media, or b) if the outbreak is not typical for influenza (atypical symptoms, very low percentage of positive rapid tests, etc...) Only the local community can decide about whether those are valid reasons.

Vaccine

Question: A Nursing home facility who wants the vaccine for its employees but their medical director won't sign the forms?

Answer: If the facility's medical director will not signoff on the protocol to administer the H1N1 vaccine, the facility could send their employees to a health department for vaccination or work out arrangements with another vaccine provider in the community, such as a hospital. (9/30/09)

Question: What is the approx target date for the info packets to be mailed out to K HELPS registrants, hospitals and VFC participants?

Answer: Most of the items are nearing the final draft stage. Some items such as the Vaccine Information Sheet are still waiting on clearance from CDC.

Question: What are the requirements to sign up on K-Helps? Several of our major employers (closed PODs) are asking if the CRI concept of pushing pills or shots is going to be used for H1N1 or is this limited to health care facilities.

Answer: Major employers can sign up on K-Helps for the H1N1 vaccine. They will need to have a Medical Director or responsible physician to order the vaccine and trained staff to manage and administer it. They should be allocated vaccine based on the target groups, after healthcare facilities, schools and similar facilities. (9/11/09)

Question: Do those individuals that have been previously vaccinated against the 1976 swine influenza need to get vaccinated against the 2009 H1N1 influenza?

Answer: The 1976 swine flu virus and the 2009 H1N1 virus are different enough that its unlikely a person vaccinated in 1976 will have full protection from the 2009 H1N1. People vaccinated in 1976 should still be given the 2009 H1N1 vaccine.

Question: One of my patients, confirmed H1N1's from this spring, wants to know if she has life time immunity to the disease. If not, is it recommended that she get the vaccine again at some point, when?

Answer: One of the most important points to address this question is to determine if the person really did have novel H1N1 influenza. We have only had about 317 confirmed cases in Kentucky so far, as most people are just being diagnosed on basis of symptoms or a rapid influenza test and aren't actually a confirmed case. In the situation where the case is not definitively laboratory confirmed, we would recommend he/she receive the vaccine. If a person does actually have a true laboratory-confirmed case of H1N1, it won't

hurt them to have the vaccine, but they are probably protected from becoming re-infected this influenza season (and probably much beyond) so don't need to be vaccinated.

Antibody made to natural influenza infection should be protective in the short-term for reinfection, but it may not be protective long-term. Influenza viruses change often, but sometimes there is cross-reactivity in antibody protection from either prior immunization or prior infection. Without repeated antigenic stimulation, antibody will wane over time. (9/11/09)

- ***Clinical Execution and Vaccine Administration***

  (Subject Matter Lead: Joy Hoskins – Joy.Hoskins@ky.gov)

Question: Will the first shipments of vaccine be Flu Mist and can it be used for all target groups?

Answer: Most of what we are being told is coming in the first shipment to states will be the live, nasal spray formulation of H1N1 vaccine. Obviously, there are restrictions on the live vaccine that are not present with the inactivated vaccine. The challenging part will be to get targeted groups vaccinated with the live vaccine, since pregnant women, children under 2, and folks with chronic illness are not recommended to receive live vaccine. Likely, we will need to focus initially on healthy healthcare workers up to age 49, healthy children and young adults 2 years through 24 years of age and healthy household caregivers of children under 6 months of age who are themselves aged 49 years or less. (9/29/09)

Question: Would a pharmacy/pharmacist complete Page 2, Section D of the Enrollment Form? Most pharmacies do not have an MD, OD, NP, PA? Is this completed page a requirement?

Answer: For pharmacists, we need the site to fill out the second page using the doctor's license # of the physician who authorizes their immunization protocols. (9/30/09)

Question: How much of a waiting period should there be between seasonal flu vaccine and the live virus forms of the H1N1 vaccine?

Answer: There should not be any "waiting period" necessary between administration of inactivated (injectable) seasonal vaccine and H1N1 vaccine or between an inactivated seasonal vaccine and a live H1N1 vaccine. However, the interval for 2 live vaccines (say, seasonal and H1N1 influenza vaccine) is usually a month apart. In addition, live seasonal flu vaccine and

live H1N1 flu vaccine are not recommended to be given simultaneously. (9/29/09)

Question: Have you seen anything regarding the Nasal Spray and the # days/hours that one who takes this must stay away from immunocompromised individuals? We have a concern that our EMS or other HCW who do not always know they are going to be in the presence of an immunocompromised individual may not wish to take this form of the vaccine.

Answer: From the PHPR:

Healthcare personnel or hospital visitors

- Who have received Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal should refrain from contact with severely immunosuppressed patients requiring a protective environment for 7 days after receipt of vaccine. Inactivated Influenza A (H1N1) 2009 Monovalent Vaccine is recommended for vaccinating household members, HCP, and others who have close contact with severely immunosuppressed persons (e.g. patients with hematopoietic stem cell transplants) requiring care in a protective environment.
- Hospital visitors who have received Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal should avoid contact with severely immunosuppressed persons in protected environments for 7 days after vaccination but should not be restricted from visiting less severely immunosuppressed patients.

From ACIP: "LAIV transmission from a recently vaccinated person causing clinically important illness in an immunocompromised contact has not been reported. The rationale for avoiding use of LAIV among HCP or other close contacts of severely immunocompromised patients is the theoretical risk that a live, attenuated vaccine virus could be transmitted to the severely immunosuppressed person."

Therefore, most healthy healthcare personnel under age 50 will be able to receive live vaccine, unless they work in units where patients are severely immunocompromised. (9/30/09)

Question: What should we recommend for children with asthma?

Answer: Anyone with asthma is at higher risk for flu-related complications, such as pneumonia. CDC has released *Asthma Information for Patients and Parents of Patients* with a variety of steps that individuals with asthma should take, including developing with their physicians an Asthma Action Plan, and getting seasonal flu and H1N1 vaccinations. (9/29/09) (http://www.cdc.gov/H1N1flu/asthma.htm)

Question: Does it depend what trimester a person is in to take the vaccine?

Answer: The **11th Edition of Epidemiology and Prevention of Vaccine-Preventable Diseases** (Pink Book), page 145, states: *A study found that the risk of hospitalization for influenza-related complications was more than four*

times higher for women in the second or third trimester of pregnancy than for nonpregnant women. The risk of complications for these pregnant women was comparable to that for nonpregnant women with high-risk medical conditions, for whom influenza vaccine has been traditionally recommended. ACIP recommends vaccination of women who will be pregnant during influenza season. ***Vaccination can occur during any trimester****.*

Question: If we don't receive an item that we asked for on the weekly order sheet do we just still keep requesting it until we get it?

Answer: Each week health departments will get a spreadsheet of doses they can order...if it is not on that spreadsheet, do not put in an order for it. For example, in week one, only live nasal vaccine may be available. Let's say 1,000 doses are allocated. Please do not send in an order for 500 syringes or 2000 of any formulation of vaccine. Send an order for no more than 1000 doses of nasal vaccine. You may send in for less than 1,000 but not more. It must be in increments of 100. If for some reason McKesson doesn't ship the full amount ordered, we think it will be held & shipped later. (9/30/09)

Question: On the enrollment form, page 2; do you need the information for all our physicians that may order the vaccine for our inpatient or outpatient population?

Answer: On the Kentucky H1N1 Vaccine Program Enrollment Form, it is requested on page 2 to list all the medical providers of the enrolling facility who can prescribe vaccines. For larger facilities like hospitals, it is only necessary to list the top medical providers of the facility who will be responsible for the H1N1 vaccination program in each facility. No need to list all medical providers who have the ability to prescribe vaccine. (9/30/09)

Question: What types of syringes, needles and ancillary supplies will come with the vaccine?

Answer: Please refer to the updated information below on the length of needles that will be included in the ancillary supply kits.

Needles:

Multi-Dose Vial Ancillary Support Kit	
NDC 08888-0003-10 Multi-Dose Vial Kit, 100 Dose Pack	
The items listed below represent the generic requirement for a multi-dose ancillary support kit. The allocation is one kit per 10 vials of vaccine.	

Item #1. Integrated Needle and Syringe unit, Sterile, Single Use, Safety engineered, 1ml or 3ml, 23 or 25 gauge, 1.0 inch or 1.5 inch	Quantity per kit: 100
Item #2. Integrated Needle and Syringe unit. Sterile, 5ml, suitable for aspirating adjuvant and transferring it to the multi-dose vaccine antigen vial.	Quantity per kit: 10
Item #3. Isopropyl Alcohol Prep Pad, individually sealed	Quantity per kit: 100
Item #4. Vaccination Card.	Quantity per kit: 100
Pre-Filled Syringe Ancillary Support Kit	
NDC 08888-0001-10 Pediatric Pre-Filled Syringe Kit, 100 Dose Pack	
NDC 08888-0002-10 Adult Pre-Filled Syringe Kit, 100 Dose Pack	
The items listed below represent the generic requirements for a pre-filled syringe ancillary support kit. The allocation is one kit per 100 pre-filled syringes.	
Item #1. Needle, FDA approved, safety engineered, sterile, luer lock, 23G, 1.0 inch or 1.5 inch	Quantity per kit: 100
Note. The Pediatric kit will contain a 25G, 1.0 inch needle	
Item #2. Isopropyl Alcohol Prep Pad, individually sealed	Quantity per kit: 100
Item #3. Vaccination Card.	Quantity per kit: 100

(Source - CDC H1N1 Vaccine Implementation Team)
The sharps containers will be supplied separately. (9/18/09)

Question: With the prefilled syringes, we have information that the needle on the pediatric dose is a 5/8". On our little ones we give injections in the

anterolateral thigh muscle and typically use a 1” needle. Do these prefilled syringes have a needle on it such that we can change it out to a 1”? Or is the syringe/needle all together and cannot be changed out? Or does the syringe even have a needle on it and we may need to have a supply of needles anyway?

Answer: On a CDC conference call, we were advised that all needles have been changed to 1". The Pediatric Pre-Filled Syringe Ancillary Support Kit will contain a 25G, 1.0 inch needle, plus all needles included in the ancillary kits will be safety needles. (9/29/09)

Needle_Length_and_ Injection_Site_for_In

Question: There is a physician here in our County who was asking me today about the makeup of the H1N1 vaccine. He wanted to know if it was an oil based vaccine.

Answer: We are not sure what he meant by an oil-based vaccine. Both the injectable and nasal-spray vaccine are being made in the same way that seasonal flu vaccine is manufactured. It does not contain an adjuvant, and last week, the manufactured vaccine was approved by the FDA. CDC advised that “None of these influenza vaccines that will be used in the U.S. during the 2009-10 season will contain adjuvants”. (9/29/09)

Question: How will we know if someone has received the H1N1 vaccine?

Answer: Here is a copy of the H1N1 "shot card" that will be included with the H1N1 vaccine packaging. Additional guidance regarding the implementation of these shots cards will be forthcoming as a part of the DPH clinical H1N1 information. (9/11/09)

Influenza Vaccination Record 082709.pdf

Question How much Thimerosal-free vaccine will be available?

Answer: It is anticipated that enough thimerosal-free vaccine in pre-loaded syringes will be available for young children and pregnant women. Various vaccine manufacturers will be producing some of the 2009 H1N1 influenza vaccine in single-dose units, which will not require the use of thimerosal as a preservative. In addition, the live-attenuated version of the

vaccine, which is administered intranasally (through the nose), is produced in single-units and will not contain thimerosal. (Updated 9/29/09)

Question: Will LHDs receive vaccine from all 4 manufacturers?

Answer: LHDs and private providers may receive vaccine from any of the FDA approved providers. Currently there are 4 with 1 more still pending. All vaccine shipments will come through McKesson. (9/29/09)

Question: How do providers address the possibility of individuals wanting vaccine and mis-representing themselves as having a high-risk condition?

Answer: Self-declaration of a high-risk condition is acceptable. LHDs and other providers have the option of having people sign self-declaration forms.

Question: Should we be looking for the first shipment of vaccine to go to the "*Subset of Target Groups During Limited Vaccine Availability*" group? If this is the case, we will not be going into schools to give, initially.

Answer: Yes, you are correct the Sub-set group will be the initial group to be vaccinated when the supply of H1N1 vaccine is in limited supply. This group does not include school aged children without medical conditions that put them at higher risk for influenza-related complications. The CDC recommendations for the initial period are online at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5810a1.htm

"If the supply of the vaccine initially available is not adequate to meet demand for vaccination among the five target groups, ACIP recommends that the following subset of the initial target groups receive priority for vaccination until vaccine availability increases (order of target groups does not indicate priority):

- pregnant women,
- persons who live with or provide care for infants aged <6 months (e.g., parents, siblings, and daycare providers),
- health-care and emergency medical services personnel who have direct contact with patients or infectious material,
- children aged 6 months--4 years, and
- children and adolescents aged 5--18 years who have medical conditions that put them at higher risk for influenza-related complications."

- ***Vaccine Administration Fees, Billing, and Reimbursement***
(Subject Matter Lead: Rosie Miklavcic– Rosie.Miklavcic@ky.gov)

Question: Is billing of third party payors/insurers permissible in public health clinics or mass vaccination sites/clinics conducted by a LHD?

Answer: It is permissible to bill third party payors/insurers in public health clinics or mass vaccinations sites/clinics conducted by, or on behalf of a public health entity. However, public health jurisdictions that do not currently have a robust billing system in place may not use PHER funds to develop billing systems. (Source - CDC H1N1 Vaccine Implementation Team, 'H1N1 Vaccine Administration Billing Q&As')(9/16/09) While LHDs may bill, they may not charge patients at the mass vaccination clinic (i.e., no cash should change hands). Please see question below.

Question: Is it permissible to charge patients a co-pay or any out-of-pocket charge in public health clinics or mass vaccinations sites/clinics conducted by a LHD?

Answer: It is not permissible to charge patients in public health clinics or mass vaccinations sites/clinics conducted by or on behalf of a public health entity. (Source - CDC H1N1 Vaccine Implementation Team, 'H1N1 Vaccine Administration Billing Q&As') (9/16/09)

Question: What is the definition of a ‘public health clinic’?

Answer: A ‘public health clinic’ is defined as a clinic that is conducted by, or on behalf of a state or local health jurisdiction and receives PHER implementation funds to administer H1N1 vaccine in any setting. For example, this may include a commercial community vaccinator (CCV) or other private provider that has a formal agreement with the public health entity. (Source - CDC H1N1 Vaccine Implementation Team, 'H1N1 Vaccine Administration Billing Q&As') (9/16/09)

Question: Is the admin fee that was talked about an option for both providers and local health departments if they want to charge?

Answer: This is very complicated and still being worked on at the national level. No firm decision has been made. Medicare/Medicaid essentially have to rule how they are handling this first. Then all the other insurers will follow suit.

Just as health plans have provided extensive coverage for the administration of seasonal flu vaccines in the past, public health planners can make the assumption that health plans will provide reimbursement for the administration of a novel (A) H1N1 vaccine to their members by private sector providers in both traditional settings e.g., doctor’s office, ambulatory clinics, health care facilities, and in non-traditional settings, where contracts with insurers have been established."

Question: Is VFC reimbursement for the H1N1 vaccine possible?

Answer: CDC is trying to connect with insurers to find out what insurers plan. AHIP has reported that insurance plans seem to want to cover it. Medicare will likely cover it as well.

Question: Regarding insurance, most health departments can't bill insurance providers and it may complicate things to ask providers or mass vaccination clinics to bill insurance.

Answer: The model CDC suggested is to have a combination of public health clinics and private provider offices vaccinate; the public health clinics would not bill but the private provider offices would. CDC plans to discuss this further. If this model isn't followed, it will be difficult to get private providers reimbursed otherwise. It may be necessary to contract with private providers to provide vaccines to high risk groups, as it will be difficult to identify high risk people at a mass vaccination clinic.

Question: Will private providers be charged for the vaccine, or will they receive it for free if they sign up on KHELPS?

Answer: Vaccine and ancillary supplies are free, but private providers will not be reimbursed by public health for administration costs. However, admin costs may be covered by many insurers.

Question: There are concerns for reimbursing providers we recruit to assist us in the vaccination efforts. Will there be a separate funding stream supplied to public health efforts for mass vaccination? Can we create a system to reimburse providers whose patients are not covered under private insurance or Medicaid?

Answer: CDC has a workgroup devoted to finance issues; they recognize it's a complex issue but the workgroup is working on all these questions.

- ***Vaccine, Adverse Events, and Inventory Tracking*** (Subject Matter Lead: Jeff Brock – Jeff.Brock@ky.gov)

- ***Logistics, Procurement, Security, and Cold Chain Distribution*** (Subject Matter Lead: Richard Dugas – Richard.Dugas@ky.gov)

Question: Where did DPH obtain the vaccine cooler/freezer units?

Answer: The vaccine refrigerators were purchased from a company called ENGLE USA and attached on of the invoices for reference. The sales rep's name is:

Denise Lilly
ENGEL USA
1555 Jupiter Park Drive, Unit 5
Jupiter, Florida 33458
Tel: 561-743-7419
www.engel-usa.com

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The price is a year old and was based on a volume discount, so it may have changed. The portable unit is Engel Portable Fridge/Freezer - 43 Qt (MT45FU1).

Another refrigerator vendor to consider is the AcuTemp company. At least one LHD has purchased equipment from AcuTemp and has been well pleased with their product. The AcuTemp website is: http://acutemp.com/temperaturesensitiveshipping/pharmaceutical.asp

Note: Franklin County HD just purchased two refrigerators from Lowe's that will work very well, and had alarms installed.

(9/16/09)

Question: How will H1N1 vaccine be distributed in Kentucky?

Answer: First of all, nothing is set in stone at this time because CDC has not finalized their plans. So, everyone must remain flexible. As of now this is what KDPH expects the H1N1 vaccine distribution in Kentucky to look like.

Initial bolus (beginning as early as 9/30/09 but more likely 10/15/09) will be 200K to 600K doses. Distribution will be from the McKesson warehouse directly to the approved providers*. (*process still under development but will mirror Vaccine For Children program) due to the minimum order size of 100 doses (set by CDC and McKesson) this may require some local or interregional distribution. For instance if x county has 15 providers that all want vaccine but none can handle 100 doses, the local HD may need to place the order and break it down for those 15 providers. KDPH does not plan on mandating this procedure. This will be completely a local/regional decision.

Now, in the early stages if KDPH doesn't have enough vaccine to ship 100 doses to each county, initial shipments may go to the regional distribution sites. There would then need to be some intraregional distribution.

One thing to note is that the 100 doses must all be the same type of doses (i.e. pediatric, infant, prefilled, LAIV, etc). So, now you can see that some clinics may in fact need to order 500 doses, one of each type, in order to be able to vaccinate all eligible clients.

Follow on shipments – about 250K doses per week.

As always – we are asking you to be prepared to receive at your regional site. McKesson is being asked to add a tremendous amount of additional vaccine into there already precarious VFC shipping process. If there is any hiccup at all, Kentucky and other states may need to revert to using regional ship to sites.

Question: What happens to orders over 100 but not even numbered (example 551)?

Answer: All orders to McKesson must be placed in increments of 100 doses. Additionally all 100 doses must be the same type of vaccine (i.e. multi-dose vials, pre-filled syringes, intra-nasal spray). You can not mix and match to get 100.
.
Your LHD will have to adjust those quantities before approving them and passing on the KDPH. It is up to the LHD and/or the facility to work out a plan to deal with the less than 100 amounts (the 51 doses). The facility may reduce their order to 500 or the 51 doses could be to be added to the LHD order and delivered to the LHD.

This is not a KDPH policy. This is a stipulation in the CDC-McKesson contract and can not be changed. (9/11/09)

Question: Will the orders to those over 100 dose providers be delivered to us or directly to the provider?

Answer: Orders over 100 doses that are approved by the LHD for delivery directly to the facility can be delivered directly to the facility from McKesson. On the other hand, if the LHD so chooses, the orders can be delivered to the LHD for distribution to the provider. (9/11/09)

Question: Our County has grown at a higher rate than most counties. Will the basis for allocation be based on current US Census Estimates for 2008, rather than 2000?

Answer: We are currently building the tool (excel spreadsheet) we will be using for allocation. We will be utilizing the 2008 est. from the US Census Bureau. (9/11/09

Question: We have a large university population and a small college in our county with several thousand students, living in the dorms. These additional students from outside our County and not listed on the census, most of whom are Kentucky residents from other counties. The university wants to know if they will be included a designated allocation for the county.

Answer: Since, initial (first two weeks) allocations will be smaller; we will probably go with a straight population based allocation. However, by week 3 we expect to begin receiving an adequate supply of vaccine. Most likely significantly more than the state has capacity to vaccinate in those 3 weeks. So, by that time we should safely be able to address any population deviations from the Census numbers such as your university population. Please be sure to remind us of this situation once you begin receiving your allocation numbers and placing your vaccine orders. (9/11/09)

Question: Our local hospital and medical community employ staff that live in surrounding counties in significant numbers. How will this be handled?

Answer: We highly encourage regional collaboration in situations such as this. If the counties in question do not have sufficient population that are in the “priority group” in the first couple weeks, they can release a portion of their allocation to your county to by utilized to vaccinate the commuter healthcare population. Work with your neighboring LHDs to address problems like this. If this solution does not work then we are comfortable that by week 3 we should be able to meet your increased need to HCWs. (9/11/09)

Question: Our county has both parents and children that commute to the county. Most of the OB/GYN's have patients from the surrounding counties. How will you accommodate for these out of county people in our allotments.

Answer: If any county feels that they have a reason to request a modification to their allocation based on an extenuating circumstance then please notify KDPH in writing or email. Since we are not aware of every such incidence like this that are based on geography. (9/11/09)

Question: What should healthcare organizations, do in terms of provider enrollment, that have facilities in multiple locations, sometimes in multiple counties?

Answer: If an organization wants to register on the K-Helps website one time and then handle all vaccine ordering and reporting centrally, they need to be prepared to handle multiple issues;

- Having enough refrigerator capacity to handle vaccine storage at their central facility,
- Facilities and proper transport capabilities to maintain the cold chain,
- Data collection issues to get reports back from their facilities to the central office, aggregated and up to the local health department, and
- The problem of different facilities in different counties or health department jurisdictions, splitting who they would report to.

This includes the big pharmacy chains, like Kroger's, Wal-Mart, Kmart, and Walgreen's. Again in these cases, I think it might be better to have each individual facility that will distribute vaccine register so that the local health department can be aware of the possibility of vaccine being distributed via these chain pharmacies in their area.

Though there may be exceptions, in most cases, we think it might be better to have each individual facility register that will distribute vaccine so that the local health department can be aware of the possibility of vaccine being distributed to all the facilities in their area. (9/11/09)

Question: What about the VA Medical Centers, will they be getting H1N1 vaccine?

Answer: The only vaccine being shipped directly to the VA Medical Centers will be to vaccinate target group federal employees (critical emergency responders, healthcare clinicians, pregnant women, and so on). Everything else – non-patient care medical center staff, patients - will come through the states. The VA clinics should register on K-Helps and be included in the LHD's allocations. (9/11/09)

Question: Is DPH going to make special arrangements for Corrections for their facilities and inmates?

Answer: The Department of Corrections has requested to order and receive their vaccine centrally. They indicated that they will then distribute the vaccine to all their facilities. DPD recommended that they coordinate with the LHDs so that they can track all vaccination within their jurisdiction. Nationally, the Federal Bureau of Prisons had requested a similar arrangement for their facilities but we are still awaiting confirmation on this. Thus, your HD will coordinate with both the state and federal correctional facilities within the county. (9/11/09)

Question: Will the vaccine be shipped to LHDs based on amount ordered or the population allocations only? We may not have storage space for everything at once.

Answer: The vaccine shipments to LHDs will be based on amount ordered by the LHD. The allocation amount is the maximum amount available to the county but you do not have to order that amount. Each facility should not order more that you can store and distribute safely.

PHER funding may be used to purchase additional equipment for proper storage and transport of vaccine. (9/11/09)

Question: Will needles and sharps containers and alcohol wipes be included in the vaccine delivery?

Answer: The ancillary supplies will be sent separately from the vaccine and will hopefully arrive close to the same time as the vaccine. HHS will provide needles, syringes, sharps containers and alcohol swabs.

Question: Will needles and sharps containers and alcohol wipes need to be ordered separate from the vaccine?

Answer: No, the ancillary supplies will be sent separately from the vaccine but do not need to be ordered separately. The ancillary supply order will be calculated based on the type of vaccine ordered (single dose vs. multi-dose).

Question: We've had several questions about PIN numbers.

Answer: Each site that will receive vaccine distribution from the McKesson warehouse will have to have a PIN number. In VACMAN each PIN has a specific location. Ex. in Pulaski County the health department has one PIN, the district office has one PIN & the school sites have one PIN. In Louisville all health departments have the one PIN per clinic...H156, H156B, H156C, H156F, H156H and H156T are currently active on the program. VACMAN cannot do this any other way & it will not let us enroll without a PIN and an address.

Anti-viral Distribution

Subject Matter Lead: Richard Dugas – Richard.Dugas@ky.gov)

Question: Who needs to be treated with antivirals for H1N1?

Answer: Not everyone with influenza-like symptoms needs to be treated, antivirals have their place, especially for high-risk folks, but they are not the

magic bullet that some clinicians and the public might seem to think. Clinicians should consider treating those who are hospitalized or at risk for severe complications from H1N1 infection.

Question: What about the supply of antivirals for H1N1?

Answer: In terms of antiviral supply, there is likely a limited commercial supply, even though the manufacturer increased production substantially over the summer. Pharmacies do not stockpile large amounts of antivirals (most use just-in-time supplies from national distributors), so knowing how much your pharmacies have "in stock" does not answer the question about when supplies are running short--- since pharmacists can order more as long as commercial supplies are available in the US.

Individual pharmacies can let the Pharmacists' Association know when they are having difficulty obtaining antivirals. When that happens, we can consider either trying to obtain antivirals from other commercial sources or breaking into the remaining government-purchased stockpile. In the meantime, government-purchased antivirals should only be used for those who are unable to afford to get their prescription filled. That written KDPH policy is close to being finalized and will use local health departments as "gatekeepers", as described on the Preparedness video teleconferences.

Question: What about antivirals for first responders and health care workers who are at high risk for complications from disease or HCW in general?

Answer: Hopefully individuals are receiving a prescription because 1) they are ill with what the clinician thinks is novel H1N1 infection or 2) they are close contacts of someone with H1N1 and are either at high-risk for complications or are a HCW/first responder. We do not recommend that these groups (first responders and health care workers), receive "just-in-case" medication courses for prophylaxis or treatment.

Question: Are we (Public Health) to pay for antivirals now for indigent patients?

Answer: Until commercial supplies are exhausted, government-purchased antivirals should only be used for those who are unable to afford to get their antiviral prescription filled. The written KDPH distribution policy is close to being finalized and will use local health departments as "gatekeepers". In the meantime, before the policy is released, we can contact Pharmacists' Association and they can direct you to a participating pharmacy if you have indigent patients who have no other means of receiving the antivirals.

Question: Who picks the pharmacy for our county? We have 2 cities in our county, so having more than one Anti-viral distribution location will certainly

benefit our citizens as many would not be able to afford to travel long distances, etc.

Answer: The Kentucky Pharmacist Association has sent out a request for pharmacies to "Opt-In" if they wish to be an antiviral dispensing location. We are working closely with the KPHA to ensure we meet everyone's needs. While KPhA will likely not be able to accommodate all requests, please let KDPH know if you have a compelling need for an additional pharmacy in your county. LHDs may want to wait to see the list of KPhA's participating pharmacies before contacting KDPH. (9/16/09)

Healthcare, Healthcare Workers

(Subject Matter Lead: Mark Sizemore - JamesM.Sizemore@ky.gov)

Personal Protective Equipment (PPE)

Modifications of Existing CDC Recommendations about Infection Control Precautions, including Facemask and N95 Respirator Use, for Healthcare Personnel (HCP)

The Kentucky Department for Public Health (DPH) recommends the following modifications to the interim guidance and interim recommendations from the Centers for Disease Control and Prevention (CDC) for the care of patients with novel H1N1 influenza in all inpatient, outpatient, and pre-hospital healthcare settings:

- Patients with a confirmed, probable or suspected case of novel H1N1 influenza can be cared for with both standard and droplet precautions, rather than airborne precautions. Such patients *may* be placed in private rooms, rather than negative pressure rooms, with appropriate use of gloves, facemasks (e.g. *surgical* masks), gowns and hand washing by HCP. Face shields or eye protection should be used, as indicated, for patient care activities with risk for exposure to blood, body fluids, secretions or excretions. Patients on droplet precautions who must be transported or are likely to come into contact with the general public should wear a facemask if tolerated and follow procedures for respiratory hygiene / cough etiquette.
- Current use of N95 respirators or higher-level respirators should be limited and confined to instances of direct airway manipulation (e.g., bronchoscopy, intubation, nasopharyngeal suction).
- If N95 respirators are either not available or in short supply, please follow the CDC **Interim Domestic Guidance on the Use of Respirators to Prevent Transmission of SARS**, May 3, 2005: http://www.cdc.gov/ncidod/sars/respirators.htm .

These Kentucky modifications of current CDC recommendations are consistent with World Health Organization recommendations and Canadian guidelines for care of cases

of novel H1N1 influenza. Other states have also implemented similar modifications since May 2009. These Kentucky modifications enable the practicable implementation of respiratory protection programs during the current influenza pandemic, considering that equipment and resource availability may be limited.

These Kentucky modifications should also be appropriate for all inpatient, outpatient and pre-hospital healthcare settings with a confirmed, probable or suspected case of seasonal influenza. (9/21/09)

2009 DPH Public Health Advisory - H1N

Question: A local ICN called and they are planning for the H1N1 vaccination of their hospital staff. They are wondering if there will be any standard data the State or the Federal government would like to see or will require to be collected on those receiving vaccination. I assume she is referring to tracking for adverse events, Guillan-Barre, etc.

> **Answer:** Providers will be required to sign a provider agreement in which they will agree to report doses administered and perhaps the ages of those who received doses. As with any vaccine, they should report any known adverse events to VAERS. Once provider agreement is finalized, we will disseminate it. In the meantime, providers can register their interest in giving vaccine at khelps.chfs.ky.gov

Clinician Guidance

Question: What type of education is being done with the physicians on H1N1 testing criteria? We are still getting patients with orders for testing but no criteria listed.

> **Answer:** DPH published an "Updated Novel H1N1 Clinician Guidance document" on 20 Aug. That document is also available online, http://healthalerts.ky.gov/swineflu/healthpros.htm. Additionally, the Kentucky Medical Association and medical specialty groups have distributed the updated guidance to their membership. Please circulate as widely as possible to providers in your jurisdiction.

Question: Is there a form with the criteria listed that the physician can check and be sent with the specimen to state lab?

> **Answer:** Not yet. However, the hospital laboratory should only submit specimens to the State Lab for novel H1N1 virus testing from those patients that meet the "*Criteria for Submission of Laboratory Specimens to the Division of Laboratory Services*" (DLS) as described in the updated clinician

guidance. Medical providers certainly can order testing for novel H1N1 virus for patients that do not meet those criteria. HOWEVER, specimens from those additional patients should be sent to national reference laboratories, e.g. Quest, rather than DLS.

Question: We were asked if we would mandate that our employees who have direct patient contact take the Novel H1N1 vaccine, when available.

Answer: Dr. Hacker has stated that the vaccine cannot be mandated, just as other recommended vaccines are not mandated. Hopefully, all HCWs will be using appropriate PPE in patient care settings. Local health department directors may want to consider furloughs for those HCW employees that decline to be vaccinated, since sick employees who spread illness could damage a department's reputation and lead to potential medicolegal issues. Attached is a declination form that was originally designed for seasonal flu.

Declination of Influenza Vaccination

Question: Is the VA going to be supplied separately or are we dependent on the state supply?

Answer: VA patients are considered part of the civilian population and will be subject to state allotment

Question: We have a patient who is positive Influenza A, and on antivirals how long should they be in isolation?

Answer: Seven days for hospitalized patients and ill staff.
"**CDC Recommendations for the Amount of Time Persons with Influenza-Like Illness Should be Away from Others**. ", http://www.cdc.gov/h1n1flu/guidance/exclusion.htm "This guidance does not apply to health care settings where exclusion period should be continued for 7 days from symptom onset or until the resolution of symptoms, whichever is longer**;** see http://www.cdc.gov/h1n1flu/guidelines_infection_control.htm for updates about the health care setting."

"**CDC recommends this exclusion period regardless of whether or not antiviral medications are used. ",** http://www.cdc.gov/h1n1flu/guidance/exclusion.htm

Question: SCL group homes, although the caregivers at these homes are not direct 'patient' providers, they are direct care providers. Would these caregivers be considered, with regards to priorities for H1N1? They provide an array of services including medications as well as personal care services, etc.

Answer: If the SCL caregivers are providing medications and assisting with activities of daily living, they are giving direct care---- just like in a long-term

care facility. It would be reasonable for you to include them as HCWS for H1N1 purposes.

CDC has definitions for Healthcare workers in a couple of publications:
From the August 21st guidance on H1N1 vaccine use,
http://www.cdc.gov/mmwr/pdf/rr/rr58e0821.pdf :

"Health-care personnel (HCP) include all paid and unpaid persons working in health-care settings who have the potential for exposure to patients with influenza, infectious materials, including body substances, contaminated medical supplies and equipment, or contaminated environmental surfaces. HCP might include (but are not limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the health-care facility, and persons (e.g., clerical, dietary, housekeeping, maintenance, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCP. The recommendations in this report apply to HCP in acute-care hospitals, nursing homes, skilled nursing facilities, physicians' offices, urgent care centers, and outpatient clinics, and to persons who provide home health care and emergency medical services (27). Emergency medical services personnel might include persons in an occupation (e.g., emergency medical technicians and fire fighters) who provide emergency medical care as part of their normal job duties."

Epidemiology/Surveillance

- ***Planning and Modeling*** (Subject Matter Lead: T.J. Sugg - Tennis.Sugg@ky.gov)

- ***Evaluation***

  (Subject Matter Lead: Jim House – JamesR.House@ky.gov)

Training and Education

(Subject Matter Leads: David Knapp and Barbara Fox – David.Knapp@ky.gov and BarbaraJ.Fox@ky.gov)

TRAIN courses & Archived Webcasts

- Summaries of the September 23 Joint ITV and H1N1 briefing are attached. To view a recorded version of this session please use the link below to access the archived webcast.

http://kennect.chfs.ky.gov/Play.dyn?m2=2ois4igzft33xz88x3y2g4dx0zd7o2hsxln3alfiasefx3wl4dw The “Private code” is: 8d7B2666


Weekly LHD H1N1 ITV Summary 092320


How to Access WEBCAST 1019283.(

Also attached information on how to access the KDPH: H1N1 Provider Enrollment and Vaccination Management Webcast. The archived TRAIN Course ID is 1019283

Please note that there are 7 downloadable documents just beneath the red triangle play button on the webcast page. Printing these and following along with the presenter will help you get the most out of this presentation.

- Much of the material is applicable to a Mass Vaccination campaign as well as a Mass Prophy campaign.

  KY DPH Strategic National Stockpile-SNS 210: Developing a Dispensing Campaign Module -1017001 has been approved for nursing continuing education as follows:
  Kentucky Board of Nursing Provider Number:
  7-0038-01-2013-702
  Contact Hours =1.2

H1N1 Grant/Funding

(Subject Matter Lead: Katie Robinson - Katie.Robinson@ky.gov)

Kentucky Department for Public Health

H1N1 Influenza

Toolkit for Clinicians

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