



**Statement before the Appropriations
Subcommittee on Labor, Health and
Human Services, Education, and Related
Agencies
United States House of Representatives**

**2009 H1N1 Influenza Preparedness and
Response**

*Thomas R. Frieden, M.D., M.P.H.
Director,
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services*

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Chairman Obey, Ranking Member Tiahrt, members of the Committee, thank you for this opportunity to update you on the public health challenges of 2009 H1N1 influenza. CDC and our colleagues throughout the Department of Health and Human Services (HHS) are working in close partnership with many parts of the federal government under a national preparedness and response framework for action that builds on the efforts and lessons learned this previous spring, as well as on preparedness training CDC has developed for pandemic influenza over the past several years. Working together with governors, mayors, tribal leaders, state and local health departments, the medical community and our private sector partners, we have been monitoring the spread of H1N1 and facilitating prevention and treatment, and have now begun a vaccination program.

Influenza is probably the least predictable of all infectious diseases and the 2009 H1N1 pandemic has presented considerable challenges—in particular the delay in production of a vaccine. Today I will update you on the overall situation, provide an update on vaccination status, and discuss other steps we are taking to address these challenges.

Tracking and Monitoring Influenza Activity

Since the initial spring emergence of 2009 H1N1 influenza, the virus has spread throughout the world. H1N1 was the dominant strain of influenza in the southern hemisphere during its winter flu season. Data about the virus from around the world—much of it collected with CDC assistance—have shown that the circulating pandemic H1N1 virus has not mutated significantly since the spring and the virus remains very closely matched to the 2009 H1N1 vaccine. This virus remains susceptible to antiviral drugs with very rare exception.

Unlike in a usual influenza season, flu activity in the United States continued throughout the summer, at summer camps and elsewhere. More recently, we have seen widespread influenza activity in 48 states; any reports of widespread influenza this early in the season are very unusual. Visits to doctors for influenza-like illness as well as flu-related hospitalizations and deaths among children and young adults also are higher than expected for this time of year. We are also already observing that more communities are affected than those that experienced H1N1 outbreaks this past spring and summer. Almost all of the influenza viruses identified so far this season have been 2009 H1N1 influenza A viruses. However, seasonal influenza viruses also may cause illness in the upcoming months—getting one type of influenza does not prevent you from getting another type later in the season.

Because of the current H1N1 pandemic, several additional systems have been put in place and modified to more closely monitor aspects of 2009 H1N1 influenza. These include the following:

- *Enhancing Hospitalization Surveillance:* CDC has greatly increased the capacity to collect detailed information on patients hospitalized with influenza. Using the 198 hospitals in the Emerging Infections Program (EIP) network and 6 additional sites with 76 hospitals, CDC monitors a population of 25.6 million to estimate hospitalization rates by age group to monitor the clinical course among persons with severe disease requiring hospitalization.
- *Expanding Testing Capability:* Within two-and-a-half weeks of first detecting the 2009 H1N1 virus, CDC had fully characterized the new virus, disseminated information to researchers and public health officials, and developed and begun shipping to states a new test to detect cases of 2009 H1N1 infection. CDC continues to support all states and

territories with test reagents, equipment, and funding to maintain laboratory staff and ship specimens for testing. In addition, CDC serves as the primary support for public health laboratories conducting H1N1 tests around the globe and has provided test reagents to 406 laboratories in 154 countries. It is vital that accurate testing continue in the United States and abroad to monitor any mutations in the virus that may indicate increases in infection severity, resistance to antiviral drugs, or a decrease in the match between the vaccine strain and the circulating strain.

- *Health Care System Readiness:* HHS is also using multiple systems to track the impact the 2009 H1N1 influenza outbreak has on our health care system. HHS and CDC are in constant communication with state health officials and hospital administrators to monitor stress on the health care system and to prepare for the possibility that federal medical assets will be necessary to supplement state and local surge capabilities. To date, state and local officials and health care facilities have been able to accommodate the increased patient loads due to 2009 H1N1, but HHS is monitoring this closely and is prepared to respond quickly if the situation warrants.

Shared Responsibility and Science-Based Guidance

Slowing the spread and reducing the impact of 2009 H1N1 and seasonal flu is a shared responsibility. We can all take action to reduce the impact flu will have on our communities, schools, businesses, and homes this fall and winter.

There are many ways to prevent respiratory infections; CDC provides specific recommendations for the general public, people with certain underlying health conditions, parents, pregnant women, caregivers, and seniors.

Some ways to combat the spread of respiratory infections include staying home when you are sick and keeping sick children at home. Covering your cough and sneeze and washing your hands frequently are also effective ways to reduce the spread of infection. Taking personal responsibility for your health will help reduce the spread of 2009 H1N1 influenza and other respiratory illnesses.

CDC has also issued 2009 H1N1 influenza guidance for schools, child care settings, colleges and universities, large and small businesses, and federal agencies. These comprehensive guidelines provide advice on how individuals and institutions can guard against the flu and mitigate its spread. Guidance has also been issued for healthcare providers about the (1) appropriate use of antiviral medications to treat patients who are at highest risk of complications from influenza and (2) infection control measures in health care settings.

Our recommendations and action plans are based on the best possible scientific information available. CDC is working to ensure that Americans are informed about this pandemic and consistently updated with information in clear language. The 2009 H1N1 pandemic is a dynamic situation, and it is essential that the American people are fully engaged and able to be part of the mitigation strategy and overall response. CDC will continue to conduct regular media briefings, available at flu.gov, to get critical information about influenza to the American people.

Vaccination Campaign

Vaccination is our most effective tool to reduce the impact of influenza. Despite rapid progress during the initial stages of the vaccine production process, the speed of manufacturing has not been as rapid as initially estimated.

CDC characterized the virus, identified a candidate vaccine strain, and our HHS partners expedited manufacturing, performed clinical trials, and licensed four 2009 H1N1 influenza vaccines all within five months. The speed of this vaccine development was possible due to the investments made by the Congress over the past four years as these contributions have helped CDC advance research and development, as well as providing the funding to ensure CDC has an adequate infrastructure to support these activities.

Pandemic planning had anticipated vaccine becoming available 6-9 months after emergence of a new influenza. 2009 H1N1 vaccination began in early October—5 months after the emergence of 2009 H1N1 influenza. Critical support from Congress resulted in \$1.44 billion for states and hospitals to support planning, preparation, and implementation efforts. States and cities began placing orders for the 2009 H1N1 vaccine on September 30th. The first vaccination with 2009 H1N1 influenza vaccine outside of clinical trials was given October 5th. As of October 30th, there were a total of 26.7 million doses available for ordering. Although significant delays in vaccine production by manufacturers have complicated the early immunization efforts, vaccine will become increasingly available over the weeks ahead, and will become more visible through delivery in a variety of settings, such as vaccination clinics organized by local health departments, healthcare provider offices, schools, pharmacies, and workplaces. CDC continues

to offer technical assistance to states and other public health partners as we work together to ensure the H1N1 vaccination program is as effective as possible.

Since September 30th, although the number of H1N1 vaccine doses produced, distributed, and administered has grown less quickly than projected, states have begun executing their plans to provide vaccine to targeted priority populations. Although we had hoped to have more vaccine distributed by this point, we are working hard to get vaccine out to the public just as soon as we receive it.

H1N1 vaccines are manufactured by the same companies employing the same methods used for the yearly production of seasonal flu vaccines. H1N1 vaccine is distributed to providers and state health departments similarly to the way federally purchased vaccines are distributed in the Vaccines for Children program. Two types of vaccine are now available: injectable vaccine made from inactivated virus, and nasal vaccine made from live, attenuated (weakened) virus.

CDC's Advisory Committee on Immunization Practices (ACIP) has recommended that 2009 H1N1 vaccines be directed to target populations at greatest risk of illness and severe disease caused by this virus. On July 29, 2009, ACIP recommended targeting the first available doses of H1N1 vaccine to five high-risk groups comprised of approximately 159 million people; CDC accepted these recommendations. These groups are: pregnant women; people who live with or care for children younger than 6 months of age; health care and emergency services personnel; persons between the ages of 6 months through 24 years of age; and people from ages 25 through 64 years who are at higher risk for severe disease because of chronic health disorders like

asthma, diabetes, or compromised immune systems. These recommendations provide a framework from which states can tailor vaccination to local needs.

Ensuring a vaccine that is safe as well as effective is a top priority. CDC expects that the 2009 H1N1 influenza vaccine will have a similar safety profile to seasonal influenza vaccine, which historically has an excellent safety track record. So far the reports of adverse events among H1N1 vaccination are similar to those we see with seasonal flu vaccine and not unexpected, but we will remain alert for the possibility of rare, severe adverse events that could be linked to vaccination. CDC and the Food and Drug Administration (FDA) have been working to enhance surveillance systems to rapidly detect any unexpected adverse events among vaccinated persons and to adjust the vaccination program to minimize these risks. Two primary systems used to monitor vaccine safety are the Vaccine Adverse Events Reporting System (VAERS), jointly operated between CDC and FDA, and the Vaccine Safety Datalink (VSD) Project, a collaborative project with eight managed care organizations covering more than nine million members. These systems are designed to determine whether adverse events are occurring among vaccinated persons at a greater rate than among unvaccinated persons. CDC has worked with partners to strengthen these vaccine safety tracking systems and we continue to develop new ways to monitor vaccine safety.

While the 2009 H1N1 influenza virus has been the focus of attention since the spring, it is important that we do not forget the risks posed by seasonal influenza viruses, which typically peak during the winter months. More than 36,000 people die each year from complications associated with seasonal flu. CDC continues to recommend vaccination against seasonal

influenza viruses, especially for all people 50 years of age and over and all adults with certain chronic medical conditions, as well as infants and children. As of the fourth week in October, 89 million doses of seasonal vaccine had been distributed. It appears that interest in seasonal flu vaccine has been unprecedented this year. Manufacturers estimate that a total of 114 million doses will be brought to the US market.

Antiviral Distribution and Use

In the spring, anticipating commercial market constraints, HHS deployed 11 million courses of antiviral drugs from the Strategic National Stockpile (SNS) to ensure the nation was positioned to quickly employ these drugs to combat 2009 H1N1 and its spread. In early October, HHS shipped an additional 300,000 regimens of the antiviral pediatric oral suspension to states in order to mitigate a predicted near-term national shortage indicated by commercial supply data. To address the shortages of pediatric antivirals, the Secretary authorized the release of the remaining 234,000 regimens of pediatric Tamiflu on October 29th. We will continue to conduct outreach to pharmacists and providers related to pediatric dosing and compounding practices to help assure supplies are able to meet pediatric demand for antiviral treatment.

Additionally, the FDA issued an emergency use authorization (EUA) on October 23rd, 2009 for the investigational antiviral drug peramivir intravenous (IV) to be used for certain hospitalized adult and pediatric patients with confirmed or suspected 2009 H1N1 influenza infection.

Closing Remarks

CDC is working hard to limit the impact of this pandemic, and we are committed to keeping the public and the Congress fully informed about both the situation and our response. We are collaborating with our federal partners as well as with other organizations that have unique expertise to help CDC provide guidance to multiple sectors of our economy and society. There have been enormous efforts in the United States and abroad to prepare for this kind of challenge. Our nation's current preparedness is a direct result of the investments and support of Congress over recent years, effective planning and action by Federal agencies, and the hard work of state and local officials across the country.

We look forward to working closely with Congress as we address the situation as it continues to evolve in the weeks and months ahead. Again, Mr. Chairman, thank you for the opportunity to participate in this conversation with you and your colleagues. I look forward to answering your questions.