



**Testimony before the
Subcommittees on Health, and Oversight and
Investigations
Committee on Energy and Commerce
U.S. House of Representatives**

**H1N1 Preparedness: An Overview of
Vaccine Production and Distribution**

Rear Admiral Anne Schuchat, M.D.

Assistant Surgeon General

**Director, National Center for Immunization and Respiratory
Diseases (NCIRD)**

Centers for Disease Control and Prevention

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Chairmen Pallone and Stupak, Ranking Members Deal and Walden, members of the subcommittees, thank you for this opportunity to update you on the public health challenges of 2009 H1N1 influenza.

The Centers for Disease Control and Prevention (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, as well as with states and localities, under a national preparedness and response framework for action that builds on the efforts and lessons learned from the past few months, this previous spring and influenza preparedness trainings conducted during the last 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, including implementing a vaccination program. CDC also has deployed staff, both domestically and globally, to assist in epidemiologic investigation of the virus and support state, local and territorial health departments with the H1N1 mass vaccination campaign.

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 and delivery of a vaccine, in part because of the slow growth of the virus during the manufacturing process. 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

One major area of effort is the tracking and monitoring of influenza activity, which helps individuals and institutions monitor and understand the impact of the 2009 H1N1 virus. 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 also remains susceptible to the antiviral drugs oseltamivir and zanamivir, with very rare exception.

Unlike 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, and higher than have been observed at any time in many recent flu seasons. 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 existing systems 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 and monitor the clinical course among persons with severe disease requiring hospitalization.

Expanding Testing Capability: Within 2.5 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 is 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.

Implementing a Flu-related School Dismissal Monitoring System: CDC and the U.S. Department of Education (ED), in collaboration with state and local health and education agencies and national non-governmental organizations, have implemented a flu-related school dismissal monitoring system for the 2009-2010 school year. This monitoring system generates a verified, near-real-time, national summary report daily on the number of school dismissals by state across the 130,000 public and private schools in the United States, and the number of students and teachers impacted. The system was activated August 3, 2009. This has helped us to calibrate our messages and guidance and may have contributed to the smaller number of school closings seen in the fall relative to those seen in the spring.

Providing Science-Based Guidance

A second major area of effort in support of individuals and institutions is to provide science-based guidance that allows them to take appropriate and effective action. 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, other community organizations, and homes this fall, winter, and spring.

There are many ways to prevent respiratory infections and CDC provides specific recommendations targeted to a wide variety of groups, including the general public, people with certain underlying health conditions, infants, children, parents, pregnant women, and seniors. CDC also has provided guidance to workers and in relation to work settings, such as health care workers, first responders, and those in the swine industry, as well as to laboratories, homeless shelters, correctional and detention centers, hemodialysis centers, schools, child care settings, colleges and universities, small businesses, and federal agencies.

With the holidays coming up, reducing the spread of 2009 H1N1 influenza among travelers will be an important consideration.

CDC quarantine station staff respond to reports of illness, including influenza-like illness when reported, in international travelers arriving at U.S. ports of entry. Interim guidance documents for response to travelers with influenza-like illness, for airline crew, cruise ship personnel and Department of Homeland Security port and field staff have been developed and posted online. As new information about this 2009 H1N1 influenza virus becomes available, CDC will evaluate its guidance and, as appropriate, update it using the best available science and ensure that these changes are communicated to the public, partners, and other stakeholders.

In preparation for the upcoming months when we expect many families and individuals to gather for the holidays, we are preparing to launch a national communications campaign to encourage domestic and international travelers to take steps to prevent the spread of flu. Plans are to display public advertisements with flu prevention messages in ports of entry and various other

advertising locations, such as newspapers and online advertisements, both before and during the upcoming holiday travel season.

Supporting Shared Responsibility and Action through Enhanced Communication

A third major area of effort is to support shared responsibility and action through enhanced communication to individuals. Our recommendations and action plans are based on the best available scientific information. 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.

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 will also help reduce the spread of infection. Taking personal responsibility for one's health will help reduce the spread of 2009 H1N1 influenza and other respiratory illnesses.

CDC is communicating with the public about ways to reduce the spread of flu in more interactive formats such as blog posts on the Focus on Flu WebMD blog, radio public service announcements, and podcasts.

Through the CDC INFO Line, we serve the public, clinicians, state and local health departments and other federal partners 24 hours/day, 7 days/week, in English and Spanish both for phone and email inquiries. Our information is updated around the clock so we are well positioned to respond to the needs and concerns of our inquirers. Our customer service representatives get first-hand feedback from the public on a daily basis. In addition to the H1N1 response, we continue to provide this service for all other CDC programs.

Prevention through Vaccination

A fourth major area of effort is prevention through vaccination. Vaccination is our most effective tool to reduce the impact of influenza. Working in close partnership with industry, HHS has led the process of developing a safe and effective 2009 H1N1 influenza vaccine, but the delivery of vaccine to the public has not been as rapid as hoped or initially estimated. CDC, in collaboration with the Food and Drug Administration (FDA), characterized the virus, identified a candidate vaccine strain, and our HHS partners expedited manufacturing, initiated clinical trials, and licensed four 2009 H1N1 influenza vaccines all within five months. The speed of this vaccine development was made possible due to investments made in vaccine advanced research and development and vaccine manufacturing infrastructure building through the office of the Assistant Secretary for Preparedness and Response (ASPR), Biomedical Advanced Research and Development Authority (BARDA) over the past four years, and in collaboration with CDC, the National Institutes of Health (NIH), and FDA. The rapid responses of HHS agencies, in terms of surveillance, viral characterization, pre-clinical and clinical testing, and assay development, were greatly aided by pandemic preparedness efforts for influenza pandemics set in motion by the H5N1 virus re-emergence in 2003, and the resources Congress provided for those efforts.

Pandemic planning had anticipated vaccine becoming available 6-9 months after emergence of a new influenza. In fact, 2009 H1N1 vaccination began in early October—just 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. Tens of millions of doses have become available for ordering, and millions more become available each week. Although the initial pace of vaccine delivery to the States has 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.

States have begun executing their plans to provide vaccine to targeted priority populations, and 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. 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 2009 H1N1 vaccine are now available: injectable vaccine made from inactivated virus, including thimerosal-free formulations, 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. In addition, ACIP recommended that local public health authorities may want to prioritize a smaller group of people while supplies are limited, in which case the following groups who are at the highest risk for infection or severe illness should receive the vaccine before others: pregnant women, people who live with or care for children younger than 6 months of age, health care and emergency medical services personnel with direct patient contact, children 6 months through 4 years of age, and children 5 through 18 years of age who have chronic medical conditions. This subset of the five target groups comprises approximately 42 million persons in the United States. 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 generally mild and are similar to those we see with seasonal flu vaccine. We will remain alert, however, for the possibility of rare, severe adverse events that could be linked to vaccination. CDC and 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 FDA and other partners to strengthen these vaccine safety tracking systems and we continue to develop new ways to monitor vaccine safety, as announced earlier this week by the Federal Immunization Safety Task Force in HHS. In addition, based on the recommendation of the National Vaccine Advisory Committee (NVAC), HHS established the H1N1 Vaccine Safety Risk Assessment Working Group to review 2009 H1N1 vaccine safety data as it accumulates. This working group of outside experts will conduct regular, rapid reviews of available data from the federal safety monitoring systems and present them to NVAC and federal leadership for appropriate policy action and follow-up.

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 U.S. market.

Reducing the Burden of Illness and Death through 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 bottles of the oral suspension formulation of the antiviral oseltamivir to states in order to mitigate a predicted near-term national shortage indicated by commercial supply data. In addition, the Secretary authorized the release of the remaining 234,000 bottles 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, and we have updated our guidance relating to general antiviral use as new information has warranted. Finally, CDC and FDA have also worked together to address potential options for treatment of seriously ill hospitalized patients with influenza, including situations in which physicians may wish to use investigational formulations of antiviral drugs for intravenous therapy. The FDA issued an emergency use authorization (EUA) on October 23rd, 2009, for the investigational antiviral drug peramivir intravenous (IV) authorizing the emergency use of peramivir for the treatment of

certain hospitalized adult and pediatric patients with confirmed or suspected 2009 H1N1 influenza infection. Physician requests for peramivir to be used under the EUA are managed through a CDC web portal.

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.