



**Testimony before the
Committee on Homeland Security and
Governmental Affairs
United States Senate**

**2009 H1N1 Influenza:
Monitoring the Nation's Response**

Kathleen Sebelius

Secretary

U.S. Department of Health and Human Services

**For Release upon Delivery
Expected at 9:30 a.m.
October 21, 2009**

Chairman Lieberman, Ranking Member Collins, members of the Committee, thank you for this opportunity to update you on the Nation's response to the 2009 H1N1 influenza. I want to assure the Committee that the Administration is taking the public health challenges seriously, and is implementing a comprehensive strategy to monitor and address H1N1 throughout this fall and winter. HHS continues to work in close partnership with virtually every part of the federal government under a national preparedness and response framework for action that builds on the efforts and lessons learned from this spring. Working together with governors, mayors, tribal leaders, state and local health departments, the medical community and our private sector partners, the federal government has been actively implementing a vaccination program and revising and refining plans and activities based on new data and information.

Tracking and Monitoring Influenza Activity

Since the initial spring outbreak of 2009 H1N1 influenza, this virus has triggered a worldwide pandemic, and was the dominant flu strain in the southern hemisphere during its winter flu season. Data about the virus from around the world have shown that the circulating pandemic H1N1 virus has not changed significantly since the spring. The virus remains similar to the virus chosen for the 2009 H1N1 vaccine, and remains susceptible to the antiviral drugs oseltamivir and zanamivir, with rare exception. As with seasonal influenza, persons with some chronic health disorders and pregnant women have a higher risk of severe disease. In contrast to seasonal influenza, elderly persons have proven less likely to contract the virus; nevertheless, many elderly persons who do contract the virus have had serious complications, so early treatment with antivirals is recommended for them, as it is for pregnant women and others at high risk for complications, and for anyone who becomes seriously ill.

Unlike our typical seasonal flu, we continued to see flu activity in the United States over the summer, notably among school-aged children and young adults. More recently, we have seen widespread influenza activity in most states. Visits to doctors for influenza-like illness are much higher than levels expected for this time of the year. We are already observing that more communities are affected than those that experienced outbreaks this past spring and summer, reflecting wider transmission and potentially causing greater impact. For example, 86 pediatric deaths related to 2009 H1N1 flu have been reported to the Centers for Disease Control and Prevention (CDC) since April 2009, a level that has only been seen at the peak of past influenza seasons. During the week of October 4 - 10, 2009, 11 deaths were reported. In each of the past three years, between 46 and 88 children died from seasonal influenza. Over the next several months, seasonal influenza viruses may circulate along with the 2009 H1N1 influenza virus, and it will not be possible to determine quickly if ill individuals have 2009 H1N1 influenza, seasonal influenza, or other respiratory conditions based on symptoms alone. Because of this, close monitoring of viruses in the United States will be critical to ensure that the best guidance about treatment and prevention of influenza can be provided.

Enhancements Made to the Tracking of Influenza Illness and Death

Because of the current pandemic, several additional systems have been put in place or modified to more closely monitor data on the impacts of 2009 H1N1 influenza. These changes 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, 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. The EIP sites also track vaccine effectiveness.

- *Expanding Testing Capability:* Within two-and-a-half weeks of first detecting the novel 2009 H1N1 virus, CDC had fully characterized the new virus, disseminated the 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 funds to maintain laboratory staff and ship specimens for testing. In addition, CDC serves as the primary support for public health laboratories around the globe and has provided test reagents to 295 laboratories in 147 countries. It is vital that accurate testing continue in the United States and abroad to monitor any changes in the virus that may indicate increases in severe infection, resistance to antiviral drugs, or a decrease in the match to circulating vaccine strains.
- *Monitoring severe illness and mortality of women who are pregnant:* Pregnant women are a group known to be at a higher risk for seasonal influenza. Similarly, data indicate that pregnant women also are at higher risk of severe disease and death from the 2009 H1N1 influenza virus. CDC is in the process of implementing a new system to collect data on severe illness (intensive care hospitalization) and mortality among pregnant women, which will improve our ability to monitor this group.

- *Aggregate Hospitalizations and Deaths Reporting Activity (AHDRA)*: To supplement several well-established influenza surveillance systems, CDC introduced an interim data collection activity to augment information on hospitalizations and deaths in 2009. This supplemental activity collects information from all 50 states to identify hospitalizations and deaths due to influenza or influenza-like-illness (ILI) nationally and within each state. Jurisdictions now can report to CDC either laboratory-confirmed or clinical pneumonia counts of hospitalizations and deaths. Initiated on September 1, 2009, this new collection activity will contribute to a more complete picture of the burden of serious influenza and pneumonia illness and deaths during the pandemic and let each state examine trends in the course of the pandemic in their areas.
- *Health Care System Readiness*: HHS is also using multiple systems to track the impact of the H1N1 outbreak on our healthcare system. HHS and CDC are in constant communication with state health officers and hospital administrators to monitor stress on the healthcare system and to be prepared in case federal medical assets will be necessary to augment state and local surge capabilities. To date, state and local officials have been able to accommodate the increased patient loads, but this is something we need to monitor very closely, and we need to be 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 influenza is a shared responsibility, and we all need to plan for what would need to be done when the flu impacts our

community, school, business, or home this fall. Given that the virus already is circulating in the United States, it is important for every American family and business to prepare their own household and business plans and think through the steps that will have to be taken if a family member or co-worker contracts the flu.

HHS has provided specific recommendations for what individuals, including people with certain health conditions at high risk of complications, parents, pregnant women, caregivers, and seniors, can do to prevent respiratory infections. We emphasize frequent hand-washing as an effective way to reduce transmission of infections. It is very important for sick individuals to stay at home, and for parents to keep children who have a fever or flu-like illness home from school, childcare, the playground, or other places children gather. Similarly, sick individuals should not get on an airplane or any public transport. Taking personal responsibility for these activities will help reduce the spread of this new virus as well as other respiratory illnesses.

HHS values the collaborative relationships established with our partners at the Departments of Homeland Security and Education and has leveraged these relationships to develop clear and actionable guidance for schools and businesses. In close collaboration with the Department of Education, CDC has released guidance and information for K-12 schools, as well as universities and colleges, advising administrators on the measures that can be taken to mitigate disease spread in educational settings while limiting the disruption of day-to-day activities and the vital learning that goes on in schools and institutions of higher education.

CDC, in close collaboration with the Department of Homeland Security (DHS), has updated its recommendations to assist businesses and other employers of all sizes. On August 19 DHS, CDC, and the Department of Commerce jointly announced guidance for businesses entitled, “*CDC Guidance for Businesses and Employers to Plan and Respond to the 2009–2010 Influenza Season*,” which is available on the flu.gov website. In early September, CDC, DHS, and the Small Business Administration released additional guidance specifically developed to help small businesses prepare for how this new virus may impact them.

CDC has also collaborated with the U.S. Office of Personnel Management (OPM) in updating its recommendations to federal departments, agencies, and employees. On October 1, HHS and OPM released guidance to help federal agencies and employees implement recommendations from CDC in planning and responding to the 2009-2010 influenza season, entitled “Preparing for the Flu; a Communications Toolkit for the Federal Workforce,” which is available on the flu.gov website.

HHS and the Department of Labor issued new guidance to address infection control and worker safety in healthcare settings. The updated infection control guidance was finalized on October 14. These comprehensive guidelines provide advice on how healthcare institutions can guard against the flu and mitigate its spread. CDC also has issued guidance for healthcare providers about the appropriate use of antiviral drugs to treat patients who are at highest risk from complications from the seasonal and 2009 H1N1 influenza.

Our recommendations and action plans are based on the best scientific information available to help our nation respond aggressively and effectively to the 2009 H1N1 virus. We are working to

ensure that Americans are informed and consistently updated with information in clear language. This is a dynamic situation, but it is essential that the American people are fully engaged so they can be part of the response. The federal government, particularly CDC, will be conducting weekly and, when necessary, more frequent briefings that will be available at flu.gov to get critical information out to the American people.

Vaccination Program

With unprecedented speed, we have completed key steps in the vaccine development process – we have characterized the virus, identified a candidate strain, expedited manufacturing, and performed clinical trials and licensed four 2009 H1N1 influenza vaccines. The speed of this vaccine development was made possible due to the investments made through the Office of the Assistant Secretary for Preparedness and Response (ASPR), Biomedical Advanced Research and Development Authority (BARDA) over the past six years in advanced research and development and infrastructure building. The rapid responses of HHS agencies, including CDC, NIH, and FDA in terms of surveillance, viral characterization, pre-clinical and clinical testing, and assay development, were greatly aided by preparedness efforts for influenza pandemics set in motion by the H5N1 outbreak in 2003.

After close collaboration with state and local authorities and the clinical community, we began the voluntary 2009 H1N1 national vaccination program at the beginning of this month. 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 Wednesday, September 30. The first vaccination with 2009 H1N1 influenza vaccine was given Monday, October 5. Vaccine shipments will continue each week into

December and, if necessary, January. Vaccine will become increasingly available 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, and meets regularly with, states and other partners to improve the effectiveness of the vaccination program.

The vaccine is available free-of-charge to the American people, but some public and private providers may charge a fee or bill insurance companies to cover the cost of administering the vaccine. The vaccine is being 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: vaccine that is injected and is made from inactivated virus, and vaccine that is given nasally and is made from live, attenuated (weakened) virus. CDC continues to work with a contractor and the states to deliver vaccine to sites across the United States.

CDC's Advisory Committee on Immunization Practices (ACIP) has recommended that the 2009 H1N1 vaccines be directed to target populations at greatest risk of illness and severe disease caused by the 2009 H1N1 virus. Mindful of these risks and the need to ensure protection of those responsible for caring for Americans when they are sick, the ACIP recommended on July 29 to target initial doses of the new 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 due to

2009 H1N1 because of chronic health disorders like asthma and diabetes or compromised immune systems. Within that target group, the ACIP noted that during times of very limited vaccine availability, the highest-risk subgroups within the target groups should be identified to receive the earliest doses of vaccine. Those subgroups include: pregnant women; people who live with or care for children younger than 6 months old; health care and emergency services personnel with direct patient contact; persons between the ages of 6 months and 4 years; and persons from ages 5 through 18 with chronic health disorders or compromised immune systems.

Since September 30, when the 2009 H1N1 vaccine was first made available to states to distribute, the number of doses that has been produced, distributed, and administered has grown steadily, and states are executing their plans for providing vaccine to high-priority populations. While modest amounts of vaccine have been made available ahead of schedule, a series of manufacturing delays has caused significant reductions in the manufacturers' projected vaccine output. These delays are affecting both the U.S. and global vaccine supplies. Although we had hoped to have more vaccine distributed by this point, ultimately everyone who wants to get vaccinated will be able to, and we are working hard to get vaccine out to the public just as soon as we receive it.

Our experience with the ups and down of the vaccine manufacturing process has made clear the need to enhance our country's vaccine manufacturing capability. Not only are we dependent on companies based in other countries, we are using decades-old technology that must be improved upon. HHS is committed to developing cell-based and other technologies to increase our vaccine manufacturing capacity. In fact, we need to make all aspects of the manufacturing process appropriate for the 21st century. This will not just help the United States; it will help the world.

It is important that when the next pandemic hits, we are better prepared to mount a speedy, agile response.

Vaccine Safety

Vaccine safety has been and continues to be a top priority for us with the 2009 H1N1 vaccine. Because the 2009 H1N1 influenza vaccine is made in the same way as seasonal influenza vaccines, we expect it to have a similar safety profile as seasonal flu vaccines, which have a very good safety track record. CDC and the Food and Drug Administration (FDA) work in cooperation with state and local health departments, healthcare providers, and other partners to closely monitor the safety of seasonal influenza and other vaccines licensed for use in the United States. CDC, FDA, and other partners will use several systems to monitor the safety of 2009 H1N1 monovalent influenza vaccine. Two primary systems that will be used are the Vaccine Adverse Event Reporting System (VAERS), which is jointly operated by the CDC and FDA, and the Vaccine Safety Datalink (VSD) project, which is managed by CDC. These systems have been strengthened, and new systems have been developed to provide more monitoring of the safety of H1N1 vaccination.

Although we expect to have enough vaccine available for all who wish to be vaccinated by the end of this year, we need to remind all Americans about the things they should continue to do to curtail the spread of this virus: washing hands, staying home if you are sick, and taking the necessary precautions to stay healthy and avoid getting sick.

While we all are very focused on the 2009 H1N1 influenza virus, it is important that we do not forget the risks posed by seasonal flu viruses, which typically peak during the winter months.

More than 36,000 people die each year from complications associated with the flu. However, we do not know the extent of disease that seasonal viruses will cause this winter or spring. CDC continues to recommend vaccination against seasonal influenza viruses, especially for all infants, children, and people at greater risk for influenza complications. As of October 9, 82 million doses of seasonal vaccine have been distributed. While some parts of the country are experiencing shortages, more doses are expected in November.

Clinical Trials

Clinical trials on 2009 H1N1 influenza vaccine began in July and are ongoing. Early information from these trials suggests that the safety profile of the vaccines trigger similar immune responses to seasonal vaccine. The clinical trials will determine, and if necessary further guide, the optimal use of these vaccines based on the levels of antibodies produced. One dose of vaccine induces what is likely to be a protective immune response in most healthy adults and children 10-17 years old. Children younger than 10 years should receive two doses of 2009 H1N1 flu vaccine. The trials are also seeking information on pregnant women and on immune-compromised individuals.

Antiviral Distribution

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 H1N1 and its spread. This action has been effective in allowing the nation to deal with spot shortages of antiviral drugs and limitations on supplies of products targeted for young children, including liquid preparations authorized for emergency use in infants less than 1 year of age. Earlier this month, HHS made available to states an additional

300,000 regimens of the antiviral pediatric oral suspension to mitigate a predicted near-term national shortage indicated by commercial supply data. Physicians treating critically ill patients with H1N1 influenza will soon have access to new antiviral drugs supported by HHS/BARDA and administered intravenously under a CDC-sponsored Emergency Use Authorization.

Major Communication Efforts

HHS continues to develop and strengthen major communication efforts as part of the public health response. This includes broad distribution of public service announcements, news reports, and other traditional media; use of social media such as podcasts, blogs, and Twitter; and frequent phone conferences with numerous physicians and other partner groups. The Department and its agencies also are collaborating with the White House on public engagement efforts to reach organizations that serve populations who are most vulnerable.

Closing Remarks

At HHS, we are working hard to understand and help control this pandemic and to keep the American people informed. We are working in close collaboration with our federal partners, health departments, and health-related organizations to make improvements and continue to build upon our current response. Our ability to respond is a direct result of the investments and support of Congress, and the hard work of state, local, tribal, and territorial public health officials and our partners in the private and not-for-profit sectors. Building strong systems to track and monitor seasonal influenza has allowed us to closely monitor the impact of this novel virus on our communities. While we must remain vigilant, at no time in our nation's history have we been more prepared to face this kind of challenge.

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