CDC Novel H1N1 Flu | The 2009 H1N1 Pandemic: Summary Highlights, April 2009-April 2010

The 2009 H1N1 Pandemic: Summary Highlights, April 2009-April 2010

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This document summarizes key events of the 2009 H1N1 pandemic and CDC's response activities for historical purposes. This document is a summary; it is not a comprehensive account of all CDC actions and activities nor is it intended to represent response efforts by other agencies and partners.

Pandemic Preparedness, Background

The 2009 H1N1 influenza (flu) pandemic occurred against a backdrop of pandemic response planning at all levels of government including years of developing, refining and regularly exercising response plans at the international, federal, state, local, and community levels. At the time, experts believed that avian influenza A (H5N1) viruses posed the greatest pandemic threat. H5N1 viruses were endemic in poultry in parts of the world and were infecting people sporadically, often with deadly results. Given that reality, pandemic preparedness efforts were largely based on a scenario of severe human illness caused by an H5N1 virus. Despite differences in planning scenarios and the actual 2009 H1N1 pandemic, many of the systems established through pandemic planning were used and useful for the 2009 H1N1 pandemic response.

CDC's response to the 2009 H1N1 pandemic response was complex, multi-faceted and long-term, lasting more than a year. This document seeks to document for the public the key events of the pandemic as they unfolded and CDC's response. The following is a summary narrative of highlighted CDC-related events from the 2009 H1N1 pandemic.

A Virus Emerges

2009 H1N1 was first detected in the United States in April 2009. This virus was a unique combination of influenza virus genes never previously identified in either animals or people. The virus genes were a combination of genes most closely related to North American swine-lineage H1N1 and Eurasian lineage swine-origin H1N1 influenza viruses. Because of this, initial reports referred to the virus as a swine origin influenza virus. However, investigations of initial human cases did not identify exposures to pigs and quickly it became apparent that this new virus was circulating among humans and not among U.S. pig herds.

Infection with this new influenza A virus (then referred to as 'swine origin influenza A virus')

was first detected in a 10-year-old patient in California on April 15, 2009, who was tested for influenza as part of a clinical study. Laboratory testing at CDC confirmed that this virus was new to humans. Two days later, CDC laboratory testing confirmed a second infection with this virus in another patient, an 8-year-old living in California about 130 miles away from the first patient who was tested as part of an influenza surveillance project. There was no known connection between the two patients. Laboratory analysis at CDC determined that the viruses obtained from these two patients were very similar to each other, and different from any other influenza viruses previously seen either in humans or animals. Testing showed that these two viruses were resistant to the two antiviral drugs amantadine and rimantadine, but susceptible to the antiviral drugs oseltamivir and zanamivir. CDC began an immediate investigation into the situation in coordination with state and local animal and human health officials in California.

The cases of 2009 H1N1 flu in California occurred in the context of sporadic reports of human infection with North American-lineage swine influenza viruses in the United States, most often associated with close contact with infected pigs. (During December 2005 – January 2009, 12 cases of human infection with swine influenza were reported; five of these 12 cases occurred in patients who had direct exposure to pigs, six patients reported being near pigs, and the source of infection in one case was unknown). Human-to-human spread swine influenza viruses had been rarely documented and had not been known to result in widespread community outbreaks among people. In mid-April of 2009, however, the detection of two patients infected with swine origin flu viruses 130 miles apart, raised concern that a novel swine-origin influenza virus had made its way into the human population and was spreading among people.

CDC remained in close contact with the international health community as the outbreak unfolded and on April 18, 2009, under the International Health Regulations (IHR) the United States International Health Regulations Program reported the 2009 H1N1 influenza cases to the World Health Organization (WHO). The cases also were reported to the Pan American Health Organization (PAHO), Canada and Mexico, as part of the Security and Prosperity Partnership of North America.

Response Ramps Up

CDC worked closely with state and local animal and human health officials on epidemiological investigations by tracing contacts of both patients to try to determine the source of their infection and by examining whether there was any link between the patients and pigs. Surveillance also was enhanced to try to detect additional cases of human illness with this virus. Based on the geographic location of the first cases, lack of contact between these cases and swine, and data collected through contact tracing and laboratory testing, CDC epidemiologists suspected that human-to-human transmission of this virus had taken place. In an article entitled Swine Influenza A (H1N1) Infection in Two Children --- Southern California, March-April 2009 published on April 21, 2009 in the Morbidity and Mortality Weekly Report (MMWR), CDC described the cases and requested that state public health laboratories send to CDC all influenza A specimens that could not be subtyped. That same day CDC responded to media inquiries related to the MMWR from medical reporters. Within a day, three additional samples of this new virus were identified in San Diego County and

Imperial County California hospitals and sent to CDC for further testing. CDC laboratory testing confirmed that these samples also were positive for the virus that would come to be called “2009 H1N1.”

By April 21, 2009, CDC had begun working to develop a virus that could be used to make vaccine to protect against this new virus (called a candidate vaccine virus). There are many steps involved with producing a vaccine – the first step is getting a good high yield vaccine virus. A high-yield vaccine virus is a sample of the virus that is used to grow the virus in mass quantities in chicken eggs. Once the virus is grown in mass quantities, the virus particles are then purified to make vaccine. Recognizing that 2009 H1N1 was a new flu virus – and, like all flu viruses, unpredictable - CDC simultaneously pursued multiple scientific methods to create a high-yield virus. A virus isolated at CDC, (called A/California/07/2009) was eventually chosen to be the vaccine virus used to make vaccine. CDC sent the vaccine virus to vaccine manufacturing companies so that they could begin vaccine production, in the event that the U.S. government should decide a vaccine was necessary.

CDC activated its Emergency Operations Center (EOC) on April 22, 2009, to coordinate the response to this emerging public health threat. Response activities were organized into a team structure according to the National Incident Management System (NIMS)These teams had different areas of focus including but not limited to: surveillance, laboratory issues, communications, at-risk populations, antiviral medications, vaccine, and traveler’s health issues. As the outbreak unfolded, team structures and staffing were periodically assessed for functionality and utility.

On April 23, 2009, samples submitted by Texas revealed two additional cases of human infections with 2009 H1N1, transforming the investigation into a multistate outbreak and response. At the same time, CDC was testing 14 samples from Mexico, some of which had been collected from patients who were ill before the first 2 U.S. (California) patients. Results from seven of the samples were positive for 2009 H1N1 and similar findings were reported for specimens submitted by Mexico to Canada. It had now become clear that cases were occurring in multiple countries and human to human spread of the virus appeared to be ongoing. That same day CDC held the first formal full press briefing to inform the media and guide the public and health care response to the rapidly evolving situation. CDC held nearly 60 press briefings during the 2009 H1N1 response.

On April 24, 2009, CDC uploaded complete gene sequences of the 2009 H1N1 virus to a publicly-accessible international influenza database, which enabled scientists around the world to use the sequences for public health research and for comparison against influenza viruses collected elsewhere, and an updated report on the outbreak was published online in the MMWR.

World Braces for Possible Pandemic

On Saturday, April 25, 2009, under the rules of the International Health Regulations, the Director-General of WHO declared the 2009 H1N1 outbreak a Public Health Emergency of International Concern and recommended that countries intensify surveillance for unusual outbreaks of influenza-like illness and severe pneumonia. Also on April 25, 2009, New York City officials reported an investigation into a cluster of influenza-like illness in a high school,

and CDC testing confirmed two cases of 2009 H1N1 influenza infection in Kansas, and another case in Ohio shortly after.

On April 26, 2009, the United States Government determined that a public health emergency existed nationwide; CDC's Strategic National Stockpile (SNS) began releasing 25% of the supplies in the stockpile that could be used to protect and treat influenza. This included 11 million regimens of antiviral drugs, and personal protective equipment including over 39 million respiratory protection devices (masks and respirators), gowns, gloves and face shields, to states (allocations were based on each state's population).

As part of the nation's pre-pandemic planning efforts, by April 2009 the Federal Government had purchased 50 million treatment courses of antiviral drugs – oseltamivir and zanamivir – for the SNS, and states had purchased 23 million antiviral regimens. After the determination of the public health emergency, FDA also took action to expand possible usage of antiviral drugs oseltamivir and zanamivir by issuing Emergency Use Authorizations (EUAs).

The EUAs allowed for use of the products in a manner different from what they were FDA-approved for. This included allowing for off-label use of:

- oseltamivir to treat children younger than 1 year of age and to help prevent influenza in children 3 months to 1 year of age, and;
- oseltamivir and zanamivir to treat patients who are symptomatic for more than two days before initiation of treatment, or who had complicated illness requiring hospitalization.

On April 27, the WHO Director-General raised the level of influenza pandemic alert from phase 3 to phase 4, based primarily on epidemiological data demonstrating human-to-human transmission and the ability of the virus to cause community-level outbreaks. Based on reports of widespread influenza-like-illness and many severe illnesses and deaths in Mexico, CDC issued a travel health warning recommending that United States travelers postpone all non-essential travel to Mexico. As in past influenza seasons, CDC urged the public and especially those people at highest risk of influenza-related complications, to protect themselves by taking antiviral drugs early in their illness when recommended by their doctor; CDC also advised that everyone take every day preventive actions like covering coughs and sneezes and staying home from work and school when ill to help reduce the spread of illness.

On April 29, 2009 WHO raised the influenza pandemic alert from phase 4 to phase 5, signaling that a pandemic was imminent, and requested that all countries immediately activate their pandemic preparedness plans and be on high alert for unusual outbreaks of influenza-like illness and severe pneumonia. The U.S. Government was already implementing its pandemic response plan. CDC continued to post and update guidance for states, clinicians, laboratories, schools, partners and the public on topics ranging from the non-pharmaceutical measures communities could take to limit spread of disease, to how to evaluate a patient for possible infection with 2009 H1N1 influenza, to how to care for children who might be sick with 2009 H1N1 influenza.

On April 30, 2009, CDC issued an MMWR Dispatch describing the initial outbreak of 2009 H1N1 influenza in Mexico. Findings in Mexico indicated that transmission in Mexico involved

person-to-person spread with multiple generations of transmission. CDC also issued an MMWR Dispatch on the outbreak of 2009 H1N1 influenza infection in a high school in New York City, that was, at the time, the largest reported cluster of 2009 H1N1 cases in the United States. The Dispatch suggested that the high school age students had respiratory and fever symptoms similar to those caused by a seasonal flu, but in addition, about half had diarrhea, which is more than expected with seasonal flu. As the details of the outbreak unfolded, the Federal response continued in high gear. Also on April 30, 2009, HHS announced that the Federal government would purchase an additional 13 million treatment courses of antiviral drugs to help fight influenza. The additional treatment courses would be added to the SNS.

As the outbreak spread, CDC began receiving reports of school closures and implementation of community-level social distancing measures meant to slow the spread of disease. School administrators and public health officials were following their pandemic plans and doing everything they could to slow the spread of illness. (Social distancing measures are meant to increase distance between people. Measures include staying home when ill unless to seek medical care, avoiding large gatherings, telecommuting, and implementing school closures).

CDC Laboratories Bolster Nation's Testing Capacity

While initial efforts were underway to develop a safe and effective vaccine to protect people against 2009 H1N1, work also was being done at CDC to help laboratories supporting health care professionals to more quickly identify the 2009 H1N1 virus in samples from patients. The real-time PCR test developed by CDC was cleared for use by diagnostic laboratories by FDA under an Emergency Use Authorization (EUA) on April 28, 2009, less than two weeks after identification of the new pandemic virus. Prior to the availability of this EUA, public health laboratories had been able to identify whether influenza A viruses were seasonal influenza viruses or were a novel strain, but the new diagnostic kits allowed labs to confirm a virus as 2009 H1N1. On May 1, 2009, CDC test kits began shipping to domestic and international public health laboratories. (Each test kit contained reagents to test 1,000 clinical specimens). From May 1 through September 1, 2009, more than 1,000 kits were shipped to 120 domestic and 250 international laboratories in 140 countries. Once labs had the test kits and verified that their testing was running properly, they were able to identify new cases more quickly than before and no longer needed to send samples to CDC for lab confirmation. The transition away from CDC lab confirmation testing didn't happen overnight though - between April 23 and May 31, 2009, CDC influenza laboratory analyzed about 5,000 influenza virus samples, five times the number that were processed in a similar timeframe in 2008, and more than during any previous influenza season. By May 18, 2009, 40 states had been validated to conduct their own 2009 H1N1 testing, with eight states having multiple laboratories able to do their own testing. CDC alerted the public that the expansion in testing capacity would likely result in a jump in the number of 2009 H1N1 cases, but that this would actually present a more accurate picture of the true scope of 2009 H1N1 influenza in the United States.

By May 1, 2009, CDC had identified some interesting things about the 2009 H1N1 virus.

- Researchers had confirmed earlier testing that the 2009 H1N1 influenza virus was a quadruple-reassortant virus, meaning that it contained virus genes that originated from four different influenza virus sources. Some of the gene segments originated from

North American swine influenza viruses, some gene segments originated from North American avian influenza viruses, one gene segment originated from a human influenza virus, and two gene segments were normally found in swine influenza viruses from Asia and in Europe.

- Testing of a number of the virus samples submitted to CDC showed that they were very similar, which means they likely originated from the same source.
- Laboratory testing showed that the 2009 H1N1 influenza virus did not have any 1918-like markers that had been associated with increased risk of severe disease.
- Testing also did not find genetic markers that were previously associated with high death rates in people infected with the avian influenza A (H5N1) virus in other countries.

On May 4, 2009, CDC shifted from reporting confirmed cases of 2009 H1N1 to reporting both confirmed and probable cases of 2009 H1N1. At that point, more than 98% of "probable" flu virus samples were testing positive for 2009 H1N1, indicating the ever-growing scale of the outbreak. Probable cases were reported to CDC by state health departments and occurred in people who tested positive for influenza A and negative for seasonal influenza A(H1N1) and A(H3N2) subtypes at their state health department laboratory, but whose samples had not had confirmatory testing for the 2009 H1N1 influenza virus.

CDC Shares Personnel, Guidance, Early Results of Studies

CDC deployed a large number of staff to the field to support the outbreak response; by May 1, 2009, 50 staff people were deployed, and that number climbed to more than 100 by May 11, 2009, before gradually declining as field teams returned from deployment to complete studies, analyze collected data, and help inform policy decisions for the prevention and control of 2009 H1N1 influenza. Over the course of the outbreak, more than 3,300 people from throughout CDC would support the response.

On May 6, 2009, CDC distributed recommendations for the use of influenza antiviral medicines to provide guidance for clinicians in prescribing antiviral medicines for treatment and prevention (chemoprophylaxis) of 2009 H1N1 influenza. CDC recommended that testing and antiviral treatment be prioritized for people with severe respiratory illness and people at high risk of complications from seasonal influenza. This included children younger than 5 years old, pregnant women, people with chronic medical conditions, and people 65 years and older.

On May 8, 2009, CDC issued an MMWR updating the situations in Mexico, the United States, and worldwide, and on May 15, 2009, CDC's Travel Health Warning recommending against non-essential travel to Mexico, in effect since April 27, 2009, was downgraded to a Travel Health Precaution for Mexico.

By this point in the outbreak, about half of all influenza viruses being detected through laboratory surveillance were 2009 H1N1 viruses, with the other half being regular seasonal influenza viruses, including seasonal influenza A H1N1, influenza A H3N2 and type B viruses. Surveillance reports indicated that the largest number of 2009 H1N1 influenza confirmed and probable cases (about 57% of cases) were occurring among people between 5 years and 24

years of age, and 41% of the hospitalizations were occurring among older children and young adults. The highest rates of hospitalization were among children younger than 5 years of age; the next highest hospitalization rate was in people 5 years to 24 years of age. Based on data from previous influenza pandemics and seasonal influenza, pregnant women had been recognized as a high-risk group early in the outbreak. Early data on 2009 H1N1 illness among pregnant women was reported in an article published as an MMWR Dispatch on May 12, 2009. This article emphasized the importance of empiric treatment (treatment without confirmatory testing) of pregnant women suspected to have 2009 H1N1. People with other previously recognized medical conditions that placed them at high risk of complications from seasonal influenza also appeared to be at increased risk of complications from 2009 H1N1 influenza. In this report, seventy-one percent (71%) of hospitalized patients had one or more underlying chronic medical conditions. Reported deaths had occurred in people ranging in age from 22 months old to 57 years old. Also, only 13% of hospitalizations had occurred in people 50 years and older, and there were few cases and no deaths in people older than 65 years, which was unusual when compared with seasonal flu.

Early results of an antibody study conducted by CDC indicated that children had no existing cross-reactive antibody to the 2009 H1N1 influenza virus, while about one-third of adults older than 60 years of age had cross-reactive antibody against the 2009 H1N1 flu virus. One possible explanation for this pre-existing antibody in older adults was that they may have had previous exposure, either through infection or vaccination, to an influenza A H1N1 virus that was more closely related to the 2009 H1N1 flu virus than contemporary seasonal influenza A (H1N1) viruses are. Data from a similar study suggested that seasonal influenza vaccine would not provide any significant protection against 2009 H1N1 influenza virus.

A Pandemic is Declared

On June 11, 2009, WHO signaled that a global pandemic of 2009 H1N1 influenza was underway by further raising the worldwide pandemic alert level to . That day, CDC held its first press conference with the new CDC Director Thomas Frieden, MD, MPH. The press conference had a total of 2,355 participants. At the time, more than 70 countries had reported cases of 2009 H1N1 infection, and community level outbreaks of 2009 H1N1 were ongoing in multiple parts of the world. The WHO decision to raise the pandemic alert level to Phase 6 was a reflection of spread of the virus in other parts of the world and not a reflection of any change in the 2009 H1N1 influenza virus or associated illness. To date, most people in the United States who had become ill with 2009 H1N1 influenza had not become seriously ill and had recovered without hospitalization.

After the WHO declaration of a pandemic on June 11, the 2009 H1N1 virus continued to spread and the number of countries reporting cases of 2009 H1N1 nearly doubled from mid-June 2009 to early July 2009. Significant levels of 2009 H1N1 illness continued, with localized and in some cases intense outbreaks occurring. By June 19, 2009, all 50 states in the United States, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands had reported cases of 2009 H1N1 infection. The United States continued to report the largest number of 2009 H1N1 cases of any country worldwide, although most people who became ill recovered without requiring medical treatment. By late June more than 30 summer camps in the U.S. had reported outbreaks of 2009 H1N1 influenza illness, and CDC released guidance for day

and residential camps to reduce the spread of influenza. At the , CDC estimated that at least 1 million cases of 2009 H1N1 influenza had occurred in the United States.

In early July, 2009, three 2009 H1N1 influenza viruses that were resistant to the antiviral drug oseltamivir were detected in three countries. (Antiviral resistance is when a virus changes in such a way that the antiviral drug is less effective in treating or preventing illnesses caused by the virus.) CDC and WHO partners continued to conduct surveillance for antiviral resistance, although instances of antiviral resistance continued to be detected very rarely.

Also in July 2009, CDC reported findings in the MMWR that indicated a striking prevalence of obesity in intensive care patients who were confirmed to have 2009 H1N1 influenza. Throughout the pandemic, CDC would continue to examine the relationship between 2009 H1N1 influenza, obesity, severe disease and other underlying risk factors.

CDC continued to work with the Council of State and Territorial Epidemiologists (CSTE) to enhance surveillance for 2009 H1N1 influenza. As 2009 H1N1 cases continued to occur through the spring and summer, the task of counting cases became increasingly difficult. On May 12, 2009, CDC transitioned from reporting individual confirmed and probable cases of 2009 H1N1 influenza to reporting aggregate counts of 2009 H1N1 lab confirmed and probable cases, hospitalizations and deaths with the launch of an aggregate reporting web site. Once the numbers of cases increased beyond the point where counting of individual cases was practical, on July 23, 2009, CDC reported the number of 2009 cases for the last time. Reporting of 2009 H1N1 hospitalizations and deaths continued. In addition, CDC continued using its traditional surveillance systems to track the progress of the 2009 H1N1 influenza outbreak. Traditional surveillance systems do not count individual cases, but instead monitor activity levels and virus characteristics through a nationwide surveillance system.

CDC worked closely with countries in the Southern Hemisphere to monitor and enhance surveillance for influenza viruses throughout the summer months. The Southern Hemisphere's influenza season began in May 2009 and countries there reported that 2009 H1N1 virus was spreading and causing illness along with regular seasonal influenza viruses. After mid-July, disease activity in most countries decreased, and by November, temperate regions of the Southern Hemisphere were reporting very little 2009 H1N1 disease activity. In general, the experience of the Southern Hemisphere with the 2009 H1N1 virus was similar to what is usually seen during a regular influenza season and did not seem to excessively impact the health care systems in the Southern Hemisphere. Also, surveillance systems did not find significant changes in the 2009 H1N1 influenza viruses circulating in the Southern Hemisphere as compared to viruses isolated from people in the Northern Hemisphere. These findings provided the U.S. with valuable clues related to what the 2009-2010 influenza season in the United States might be like. Importantly, the lack of significant changes in the virus indicated that the 2009 H1N1 vaccine being manufactured would closely match the currently circulating 2009 H1N1 viruses and likely provide people with good protection against 2009 H1N1 influenza.

Ongoing Surveillance & Response

2009 H1N1 influenza summer activity peaked in the United States during May and June and

declined during July and early August. However, levels of influenza activity would remain above normal throughout the summer months with localized outbreaks. During the last two weeks of August, 2009 H1N1 influenza activity again began to increase United States.

In August 2009, CDC reported an additional two instances of oseltamivir-resistant virus infection in two immunosuppressed patients in Seattle, Washington. Later, in mid-September, CDC reported two additional cases of oseltamivir-resistant 2009 H1N1 influenza in two summer campers in North Carolina. CDC and partners continued to carefully track 2009 H1N1 influenza antiviral resistance. As of June 2010 the 2009 H1N1 virus remains susceptible to the antiviral drugs oseltamivir and zanamivir, with rare exception. Cases of antiviral resistance are carefully tracked and updated numbers are posted each week as part of the CDC publication FluView.

In late August, CDC began working with the commercial supply chain (manufacturers, distributors, retailers) for certain influenza countermeasures to monitor national inventory levels of critical supplies (antivirals and respiratory protective equipment) on a weekly basis. This visibility provided important data to guide SNS decision-making leading to the release of additional SNS countermeasures.

FDA and the manufacturer of the antiviral drug Tamiflu® (oseltamivir) recognized that commercial and stockpiled supplies of Tamiflu® oral suspension (liquid formulation meant for children) were limited in October 2009. CDC worked with partners to reach pharmacists with background information, updates on antiviral drug supplies, and instructions on how to compound oral suspension from Tamiflu® capsules meant for adults (Compounding is the mixing of drugs by a health care professional to fit the unique needs of the patient). CDC also provided instructions for parents and caregivers on how to make a medicine mixture for their child using adult Tamiflu® capsules and thick, sweetened liquid. CDC also analyzed related surveillance data and based on the analysis over 500,000 bottles of pediatric oral suspension were distributed from the CDC SNS to states to fill production gaps and meet the increasing demand for the formulation.

On October 23rd, 2009, FDA issued an Emergency Use Authorization (EUA) for Peramivir IV. Peramivir IV is an investigational intravenous antiviral drug used to treat people who have been hospitalized due to severe flu illness. This drug was held in the Strategic National Stockpile (SNS) and distributed by CDC under an EUA. Licensed clinicians were able to request this product through the CDC website electronic request system, and product was delivered directly to hospital facilities. Also in October, HHS authorized the release of an additional 59.5 million N95 respirators.

CDC closed out reports of 2009 H1N1 hospitalizations and deaths for the 2008-09 season in late August. On August 30, 2009, reporting modifications were implemented to allow states to report hospitalizations and deaths associated with any influenza or to report hospitalizations and deaths using a pneumonia and influenza syndromic case definition through the Aggregate Hospitalizations and Deaths Reporting Activity (AHDRA). This change in reporting was implemented in order to provide a fuller picture of the burden of serious flu illness and deaths during the pandemic. The new reporting season for the 2009-2010 flu season began on August 30, 2009, and the first new numbers for the 2009-2010 season were reported in the September 11, 2009 issue of FluView.

Over the course of the pandemic, CDC refined and revised its surveillance methods, eventually developing a methodology based on surveillance data to estimate the range of 2009 H1N1 cases, hospitalizations and deaths in the United States. CDC released its first official estimates for 2009 H1N1 cases, hospitalizations and deaths on November 12, 2009, and updated these on December 10, 2009, January 15, 2010, February 12, 2010, March 12, 2010, April 19, 2010 and for the final time on May 14, 2010.

2009 H1N1 Vaccination

The emergence and spread of the 2009 H1N1 virus resulted in extraordinary influenza-like illness activity in the United States throughout the summer and fall months of 2009. During this period, influenza activity reached its highest level in the reporting week ending October 24, 2009, with 49 of 50 states reporting geographically widespread disease. A cornerstone of the U.S. Government response to the 2009 H1N1 pandemic was the launch of the national influenza 2009 H1N1 vaccination campaign that began in October.

Much activity led up to the launch of the vaccination campaign.

Starting in early June 2009, weekly calls were held to provide state and local planners with vaccine-related updates, and on July 8, 2009, CDC issued guidance for state and local public health departments to assist them in planning for the 2009 H1N1 influenza vaccination campaign. On July 9, 2009, the Department of Health and Human Services, the Department of Homeland Security, the Department of Education, and the White House held an influenza preparedness summit for federal, state, local and tribal officials to discuss existing pandemic plans, lessons learned, and preparedness priorities. At the summit, the Federal government announced the availability of $350 million in supplemental funding for use by state, local and territorial health departments to bolster their response activities to the 2009 H1N1 influenza pandemic and strongly encouraged state, tribal and local partners to be ready to begin a 2009 H1N1 influenza immunization program by mid-October 2009.

The 2009 National Influenza Vaccine Summit, a partnership of public and private stakeholders committed to achieving the *Healthy People 2010* goals for influenza vaccine, convened on June 29. During the 2009 Summit, attendees were provided updates by experts in several professional fields, including private medicine, public health, health communication, vaccine manufacturing, vaccine distribution, and vaccine-related policy. CDC has been a cosponsor of this event, along with the American Medical Association, since 2001.

In preparation for the 2009 H1N1 influenza immunization program, on July 22, 2009, the National Institutes of Health (NIH) announced the start of a series of clinical trials to test pilot lots of two manufacturers' versions of 2009 H1N1 influenza vaccine in healthy people, as well as people with underlying health conditions like asthma and HIV. Preliminary results from the clinical trials were announced publicly.

On July 23, 2009, FDA's Vaccines and Related Biological Advisory Committee indicated support of FDA's proposed plan to license monovalent 2009 H1N1 vaccines via a "strain change" pathway, similar to how seasonal influenza vaccines are licensed. This meant the 2009 H1N1 vaccine would be made in the same way using the same standards already in place for seasonal vaccines; it also allowed licensure to proceed more quickly since it did not

require immunogenicity data or additional safety (except for the live attenuated vaccine) data for licensure.

On July 29, 2009, the Advisory Committee for Immunization Practices (ACIP) met to make recommendations for 2009 H1N1 vaccine. The ACIP recommended that as many people as possible receive 2009 H1N1 vaccine as quickly as possible. Certain groups of people were targeted to receive initially limited supplies of the 2009 H1N1 vaccine based on epidemiologic and virologic data indicating they were at higher risk for infection or for severe influenza complications. The initial target groups for vaccination were estimated to consist of about 159 million people and included: pregnant women, people who live with or care for infants younger than 6 months of age, health care and emergency medical services personnel, infants 6 months through young adults 24 years of age, and adults 25 through 64 years of age who are at higher risk for 2009 H1N1 complications because of chronic health disorders or compromised immune systems. The ACIP also recommended that local public health authorities and health care practitioners have flexibility to determine at the local level how quickly and when to expand vaccination to other groups because vaccine availability and demand would likely vary by area.

CDC convened three public engagement sessions in mid-August in ten regions of the United States with the purpose of soliciting citizen input into vaccination planning. The public provided opinions to CDC regarding how vaccine should be provided in the U.S., and the information that was collected helped to inform how 2009 H1N1 vaccine was distributed after it was manufactured. Ultimately, it was decided that vaccine should be distributed as soon as it was ready so that people could be protected against influenza as soon as possible, versus waiting to distribute vaccine until large quantities were prepared.

In late August, CDC published a study in the MMWR that summarized an investigation of laboratory-confirmed cases of 2009 H1N1 influenza identified during April 24-July 25, 2009 in Chicago, Illinois. The study found that the overall attack rate was highest among children aged 5-14 years (147 per 100,000 population), which was 14 times higher than for adults older than 60 years of age. A total of 205 (13%) patients were hospitalized, with the highest rate observed among children aged 0-4 years (25 per 100,000), followed by children aged 5-14 years (11 per 100,000). These findings would also provide input into vaccination strategy.

By the end of August 2009, prototype vaccines to prevent 2009 H1N1 virus had been developed but were not yet licensed. Production of the enormous quantities of vaccine necessary to protect the entire U.S. population was underway. CDC expanded its contract for the childhood Vaccine for Children program in the United States (McKesson Specialty Distribution), to provide centralized distribution of 2009 H1N1 vaccine. Available vaccine supplies were allocated to states proportional to their total populations and shipped to public and private provider vaccination sites based on orders placed by the states. Participating providers were asked to sign a Provider Agreement assuring they intended to meet state requirements for administering vaccine.

On September 3, 2009, CDC published in the MMWR a study that had analyzed data related to 2009 H1N1 influenza pediatric deaths reported to CDC from April to August, 2009. Data showed that as of August 8, 2009, 477 deaths with laboratory confirmed 2009 H1N1 flu in the United States had been reported to CDC, including 36 children younger than 18 years of age.

Sixty-seven percent (67%) of children who died with 2009 H1N1 influenza had at least one high-risk medical condition. CDC continued to urge parents to recognize 2009 H1N1 in their children early and to seek medical attention when needed. CDC also reiterated that all children 6 months or older and caregivers of children younger than 6 months should receive the 2009 H1N1 vaccine when it became available.

On September 10, 2009, the HHS Secretary and CDC Director joined the National Foundation for Infectious Diseases (NFID) in a news conference to stress vigilance against seasonal influenza in an unusual season and urged Americans to get their seasonal flu vaccine early. In addition to NFID, HHS and CDC, the news conference was held in collaboration with the American Medical Association (AMA), American Academy of Pediatrics (AAP), American College of Physicians (ACP), AARP, and the National Influenza Vaccine Summit.

On September 15, 2009, the Food and Drug Administration (FDA) announced its approval of four 2009 H1N1 influenza vaccines, and later, on November 16, FDA announced its approval of a fifth 2009 H1N1 vaccine to protect against the 2009 H1N1 flu virus.

The NIH announced on September 21, 2009, that early results from clinical trials of 2009 H1N1 influenza vaccine in children looked promising. Preliminary analysis indicated that the vaccines were safe, and that only one dose of 2009 H1N1 vaccine for the majority of 10 to 17 year olds would be needed to generate a sufficient immune response to be protective against 2009 H1N1 influenza virus, but younger children generally had a less robust early response to the vaccine. CDC recommended that children younger than 10 years receive two doses of 2009 H1N1 influenza vaccine. Results of trials conducted among adults were later published in December, and the data indicated that the immune response among vaccinated adults was excellent. The safety data from these trials also indicated that vaccine side effects were similar to those seen with the seasonal flu vaccines.

On September 30, 2009, states were able to place their first orders for the 2009 H1N1 vaccine; forty-seven states placed orders on that day, and by October 9, 2009, all states and the District of Columbia had placed orders for vaccine. The first doses were administered on October 5, 2009.

Because initial supplies of vaccine were limited, most state and local health departments requested that vaccine be given only to those in the initial target groups, and many restricted use to those in sub prioritization groups that had also been outlined by ACIP. The first six weeks after vaccines were initially released where characterized by high demand for vaccine and limited availability. On October 23, the ACIP discussed pandemic vaccine issues, including suitability of the initial target groups developed in July 2009, and concluded that the July guidance remained appropriate. The ACIP continued to emphasize the role of local decision-making in determining when to begin offering vaccine to persons outside initial target groups.

As vaccine supply increased, by late November and early December most states had begun easing restrictions for 2009 H1N1 vaccine use, and by late December vaccination had been opened up to anyone who wanted it. Also beginning in December 2009, the HHS Center for Faith-Based Neighborhood Partnerships partnered with the HHS Regional Offices to host eleven teleconferences to engage community and faith-based organizations in the 2009

H1N1 flu response. Since most states were easing vaccination restrictions, these calls presented an opportunity to remind key partners that they should check with their local health departments to determine availability of vaccine. By the week of December 22, distribution of 2009 H1N1 vaccine had been opened up to retail pharmacies so that they could place orders for vaccine directly, thereby expanding the reach and availability of vaccine.

In December 2009, CDC published in the MMWR preliminary safety results for the 2009 H1N1 vaccines from the first months of reports received through the U.S. Vaccine Adverse Event Reporting System (VAERS), a national voluntary reporting surveillance system and data from the Vaccine Safety Datalink. Results indicated that the vast majority (95%) of adverse events reported to VAERS after receipt of the 2009 H1N1 vaccine were not serious (e.g., soreness at the vaccine injection site). Of the 3,783 reports, 204 (5%) were reports that involved what would be coded as serious health events (defined as life threatening or resulting in death, major disability, abnormal conditions at birth, hospitalization, or extension of an existing hospitalization). The percentage of reports involving what would be considered serious health events was not substantially different between 2009 H1N1 and seasonal influenza vaccines.

The 2009 H1N1 influenza vaccine was manufactured in several formulations, using the same manufacturers and the same manufacturing practices used to produce seasonal influenza vaccine. Monitoring the safety of the flu vaccine continues to be a top priority. CDC and the Food and Drug Administration (FDA) worked with other agencies to establish and enhance existing surveillance systems to rapidly detect any unexpected adverse events among persons who are vaccinated and to adjust the vaccination program, if necessary, to minimize risks and maximize benefits from vaccination. Two important systems used to monitor vaccine safety that have been active for 20 years, are the Vaccine Adverse Events Reporting System (VAERS), jointly operated between CDC and FDA, and the Vaccine Safety Datalink (VSD) , a collaborative project between the CDC and eight managed care organizations covering more than nine million members(about 3% of the US population). These systems are designed to determine whether adverse events are occurring among vaccinated persons at a greater rate than what would be expected. CDC worked with FDA and other partners to strengthen these vaccine safety monitoring systems and develop new ways to monitor vaccine safety. 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 conducts regular, rapid reviews of available data from the federal safety monitoring systems and presents them to NVAC and federal leadership for appropriate policy action and follow-up.

Also in December 2009, HHS joined with the Ad Council to launch a new nationwide Public Service Announcements campaign called *Together We Can Fight the Flu* that encouraged Americans to get vaccinated against the 2009 H1N1 virus. The week of December 18, 2009 marked the first 100 million doses of 2009 H1N1 vaccine available for ordering.

The year 2010 began with the National Influenza Vaccination Week (NIVW). NIVW is a national observance that was established to highlight the importance of continuing influenza vaccination after the holiday season into January and beyond. The President of the United States proclaimed the week of January 10-16, 2010, National Influenza Vaccination Week,

and encouraged all Americans to observe the week by getting the 2009 H1N1 flu vaccine and by asking their families, friends and coworkers to do the same. CDC and HHS - in conjunction with the states and many other partners, both public and private - launched a comprehensive NIVW campaign with the objective of raising vaccination awareness, providing educational opportunities, free resources, as well as vaccination clinics. Every year, certain days during NIVW are designated to highlight the importance for certain groups; this year's Week was dedicated to highlighting the importance of vaccination for the general public and health care workers, people with chronic health conditions that put them at high risk of serious influenza-related complications, children, pregnant women, and caregivers of infants less than 6 months old, young adults 19 through 24 years old, and people 65 years and older. For example, the events on Tuesday, January 12 centered on people with chronic medical conditions that put them at higher risk of serious influenza-related complications. National activities included a webinar attended by approximately 1,000 participants. This joint effort was hosted by HHS, CDC, the American Cancer Society, the American Diabetes Association, and the American Lung Association. In addition, Secretary Sebelius participated in two press conference calls announcing new public service announcements (PSAs) tailored to African American and Native American audiences. The Director of the Indian Health Service joined the Secretary in stressing the importance and benefits of vaccination.

On January 15, 2010, CDC published an article in the MMWR on influenza A (H1N1) 2009 monovalent vaccination coverage in the United States between October and December 2009. Results of the study indicated that efforts to get available vaccine to target groups had largely succeeded. Early on during the 3-month period, 85% of available vaccine reached people within those initial target populations. By the end of December, with many programs expanding their vaccine efforts to all populations, 74% of all vaccine given during the program had gone to people in the initial priority groups.

On February 18, 2010, the World Health Organization (WHO) published recommendations for the composition of influenza virus vaccines for the upcoming season in the Northern Hemisphere (November 2010-April 2011). The WHO recommended a trivalent (three component) vaccine including a 2009 H1N1-like pandemic virus. In February of 2010, the components of the 2010-2011 influenza vaccine were announced. The 2010-2011 flu vaccine will protect against a 2009 H1N1-like virus in addition to an influenza A H3N2 virus and an influenza B virus.

The United States experienced its second wave of 2009 H1N1 activity in the fall with activity peaking during the second week in October. After that, activity declined quickly to below baseline levels in January, but persisted for several more months at lower levels. However, by May, influenza activity levels in the United States were low across key flu indicators. Reporting for the 2009-2010 influenza season was finalized on May 28, 2010. Even as flu activity reached normal summer-time levels in the U.S., CDC continued to recommend influenza vaccination, particularly for high risk persons, because of reports of ongoing sporadic cases of 2009 H1N1, ongoing spread of 2009 H1N1 in the Southern Hemisphere and the possibility that 2009 H1N1 viruses might circulate early during the upcoming flu season.

CDC Communication Activities During the 2009 H1N1 Pandemic

The CDC response to the 2009 H1N1 pandemic was led by science and continually evolved to meet the nation's needs as events unfolded and as more information became available. However, a consistent underlying communications strategy underscored the entire CDC response. The strategy is based on the emergency risk communications principles of quickly, proactively and transparently communicating accurate information to the public and to partners. This strategy included CDC clearly stating its goals and actions in response to the evolving situation and acknowledging what was **not** known, as well as what was known. Another important part of the strategy was CDC setting the expectation that information and advice would change rapidly as the situation evolved. From the earliest days of the pandemic, CDC regularly articulated its goals to "reduce transmission and illness severity, and provide information to help health care providers, public health officials and the public address the challenges posed by the new virus." Throughout the response, in an effort to provide the most helpful information in the most effective ways possible, CDC drew on existing knowledge but also worked with partners to conduct ongoing scientific research and evaluation of people's knowledge, attitudes and practices related to a number of topics including 2009 H1N1 flu, infection control guidance, and vaccine.

Especially during the early days of the outbreak, the release of information from CDC and exchange of information with partners was conducted on a 24-hour cycle. This included frequent updates to media and the public, the consistent use of a core group of spokespersons, daily information outreach to partners, and rapid establishment and ongoing maintenance of an extensive Web site dedicated specifically to the emergency response for 2009 H1N1 flu. The goal was not only to be as transparent as possible in all activities related to managing the public health response, but also to maintain credibility and continue to be a trusted source of information for the public and for partners.

Beginning early in the response and continuing throughout the year and into 2010, special care was taken to keep state and local public health partners informed of CDC's activities. Key messages were regularly provided to help maintain consistent, clear communication across the response. Special care also was taken to regularly collect feedback from state and local public health partners to help ensure that CDC recommendations were finely tuned to what was happening in the field. Regularly scheduled conference calls with the Association of State and Territorial Health Officials, the National Association of City and County Health Officials, and the National Public Health Information Coalition proved to be an effective way to share information. In addition, on April 24, 2009, CDC held the first of more than 30 Clinician Outreach and Communication Activity (COCA) calls presented on a variety of 2009 H1N1-related topics. COCA is designed to reach a diverse group of health care providers and provide a system through which clinicians can communicate their educational needs to CDC and receive answers to questions about related emerging diseases. At the peak of the 2009 H1N1 response, COCA had more than 41,100 listserv subscribers.

CDC also worked hard to keep the policy community informed. CDC provided responses to congressional requests for information and briefings on 2009 H1N1-related issues, and also provided email and web-based informational updates as the pandemic unfolded. In all, CDC participated in 14 hearings, provided technical assistance in another 12 hearings, issued over three dozen 2009 H1N1 newsletters to policymakers, arranged for over 40 congressional briefings or speaking engagements and fielded over 350 congressional inquiries during the pandemic.

There was a concerted effort to get information out as soon as possible and to keep the public and partners aware of developments as they unfolded, even as guidance was changing quickly. For example, when relatively few cases of human infection with this virus were lab confirmed and severity of the pandemic was not known, on April 28, 2009, CDC posted guidance for schools and advised that they close if they had a suspected or actual case of the flu in order to lessen the risk of spreading 2009 H1N1 into their communities. As more information became available suggesting a lower risk of severe illness and death from 2009 H1N1, six days later the recommendation was changed to recommend against school closure for community mitigation purposes.

The development of CDC guidance is an example of the collaborative communication and sharing of information that took place between CDC, HHS, other federal agencies, and external partners. Development of appropriate guidance often relied on CDC communication with many external partners several times a week, with the goal of achieving consensus on what the best practice would be given the best science currently available. For example, CDC worked with representatives from a number of organizations including but not limited to Council of State and Territorial Epidemiologists (CSTE), National Association of County and City Health Officials (NAACHO), American Academy of Pediatrics (AAP), American Academy of Family Physicians (AAFP), American College of Obstetricians and Gynecologists (ACOG), Association of State and Territorial Health Officials (ASTHO), American College of Physicians (ACP), Infectious Diseases Society of America (ISDA), American Academy of Pediatrics (AAP), Food and Drug Administration (FDA) and World Health Organization (WHO), during the development of guidance related to everything from surveillance systems to the appropriate use of antiviral drugs during the pandemic. On the topic of vaccination, these discussions helped inform decision-making by the Advisory Committee on Immunization Practices (ACIP).

Apart from ongoing collaboration between CDC and its external partners, the communications response for 2009 H1N1 flu also was characterized by ongoing, close coordination between CDC's communicators and its scientists to ensure that messages stayed scientifically accurate. Also, CDC communicators took time to regularly analyze feedback from a variety of external sources, including polls and surveys, in order to ensure that CDC's messages were clear.

CDC provided a steady stream of information to audiences across the spectrum: from the public to pharmacists to laboratorians to international partners and countries around the globe. Information provided by CDC reached a myriad of audiences through a variety of channels including but not limited to: a 24-hour information hotline, press briefings for the media, dissemination through health alert networks, daily postings (including video and audio podcasts) to the CDC 2009 H1N1 web site, regular updates on Facebook and Twitter, and further outreach by partners and partner organizations to their own audiences, just to name a few channels. For example, in November 2009, CDC kicked off a national travelers' health public awareness campaign and urged travelers to plan ahead and stay informed about what to do if they got sick while they were away from home. The campaign used a variety of media, including informational posters distributed at over 300 ports of entry in the United States, national radio and print advertising, and social media and online outreach, which culminated in over 80 million exposures. CDC also coordinated with HHS and the Flu.gov web site and posted communication toolkits for the 2009-2010 influenza season for businesses, employers, childcare groups and institutions of higher education.

The CDC 2009 H1N1 influenza and seasonal influenza vaccination campaign was made up of multiple outreach efforts including placement of articles geared to numerous audiences like parents and young adults, in high-profile media outlets. Article placements led to nearly 403 million overall impressions. Other national outreach efforts made via social media tools, radio ads, two television public service announcements (PSAs), online media banners, and city bus ads. Numerous print materials in multiple languages were made for partners to distribute and were downloaded tens of thousands of times. Special audiences identified for additional print materials included Native Americans, African Americans, Hispanics, pregnant women, young adults, first responders, and health care workers.

In addition to materials provided for the 2009 H1N1 and seasonal influenza vaccination campaign, CDC provided other key materials in multiple languages. For example, the entire English-language 2009 H1N1 web site was mirrored in Spanish. In addition, key tools and resources were created in Chinese, Vietnamese, Korean, French, German, Arabic, Russian, Amharic, Farsi, Somali, Karen, Burmese, Cambodian, and Kirundi.

In all, between April 2009 when 2009 H1N1 flu first emerged and April 2010, CDC held 60 related media events – 39 press briefings and 22 telebriefings – for a total of more than 35,000 participants. CDC also hosted its first ever two-day workshop for the news media on the subjects of both 2009 H1N1 influenza and seasonal influenza in late August. Originally conceived to include 12 members of the news media, the attendance grew to over 40 journalists from national, regional and local news outlets representing radio, television, newspapers, magazines, and online news media. Speakers at the event included the Secretary of Health and Human Services, the CDC Director, influenza experts, vaccine safety experts, and laboratory experts. The CDC hotline (1-800-CDC-INFO) responded to more than 211,000 related inquiries from the general public and health care providers, and the CDC 2009 H1N1 web site had more than 219,595,000 page views. Also, the number of CDC Facebook fans rose to more than 55,000 fans and the CDC emergency profile on Twitter was tracked by more than 1,200,000 followers.

Related Links

Update: Influenza Activity --- United States, 2009--10 Season
(BARDA) HHS 2009 H1N1 Vaccine Development Activities
(FDA) Influenza (Flu) Antiviral Drugs and Related Information
HHS 2009 H1N1 Vaccine Development Activities
H1N1 Influenza Vaccine Development Process
The Science behind Developing the H1N1 Vaccine
Pan American Health Organization (PAHO): Pandemic (H1N1) 2009
World Health Organization (WHO): Pandemic 2009 H1N1
FDA 2009 H1N1 (Swine) Flu Page
Medical Devices and Flu Emergencies
H1N1: Meeting the Challenge
(American Public Health Association) Public Health, APHA Respond to H1N1 Virus
(Association of Public Health Laboratories) Novel H1N1 Flu
(The Association of State and Territorial Health Officials) Responding to a virulent pandemic
(The Public Health Informatics Institute (PHII))

National Association of State and City Health Officials, Programs and Activities, H1N1