

U.S. Department of Health and Human Services Secretary Kathleen Sebelius and U.S. Department of Homeland Security Secretary Janet Napolitano issued the following statements in response to the World Health Organization's (WHO) decision to raise the pandemic threat level on the novel H1N1 virus.

"Today's decision by the WHO was expected and doesn't change what we have been doing here in the United States to prepare for and respond to this public health challenge. Once we saw how fast this virus was spreading, we activated our pandemic plans and started doing all the things we needed to do to keep the public as safe and secure as possible," said Secretary Sebelius. "What this declaration does do is remind the world that flu viruses like H1N1 need to be taken seriously. Although we have not seen large numbers of severe cases in this country so far, things could possibly be very different in the fall, especially if things change in the Southern Hemisphere, and we need to start preparing now in order to be ready for a possible H1N1 immunization campaign starting in late September."

"We responded to the H1N1 outbreak from the outset with the presumption that a pandemic was likely, so this decision comes as no surprise. We acted aggressively to stay ahead of the virus as it spread across the country. Now our challenge is to prepare for a possible return in the fall," said Secretary Napolitano. "The Obama Administration has been working together across the government and will continue to do so over the weeks and months ahead to keep the American people safe. We are reaching out to our partners in state and local government, in school districts and the private sector to urge them to modify and update their pandemic plans. We are working with our scientists to test and prepare a possible vaccine. And we are working with governments around the world to share what we know and learn from what is happening in their countries."

TALKING POINTS ON LEVEL SIX

The WHO—World Health Organization—may have changed what they are calling the current H1N1 outbreak but nothing has changed in this country in terms of the Administration's response.

Our goal since the outbreak began has been to try and step one step ahead of this unpredictable virus and do the planning and preparation necessary to keep Americans safe and secure.

We have been preparing for a pandemic and been implementing our pandemic response plan for the past few weeks here in this country - sending anti-virals to the states, beginning the work necessary to produce a vaccine, working with

state and local officials on community mitigation strategies and monitoring and tracking the virus around the country,

The change in the WHO pandemic alert level to phase 6, will have little impact on our response in the United States. From the beginning, we have assumed an aggressive public health approach to this outbreak.

Although the virus continues to spread to other countries, the disease continues to be a mild one for the most part. Health Officials are not seeing significant changes in the virus in samples from various countries.

The WHO pandemic phase designation is based on geographic spread of the influenza virus, not on the severity of the illness.

Today's WHO announcement should be an alert to countries in the southern hemisphere that the virus is likely present and health authorities should heighten their surveillance activities and review their pandemic plans.

Here in the US, we are working hard across the government to be prepared for what happens in the fall with H1N1 when the traditional flu season starts. We are preparing to have a vaccine tested and ready to go should the science determine we need to begin an immunization campaign.

Q&As on the WHO Declaration of Pandemic Phase 6 for Novel H1N1

PHASE 6

What do the WHO phases mean?

The WHO phases are based on the geographical spread of a novel influenza virus. As "pandemic" means worldwide epidemic, a WHO Phase 6 means that the virus is spreading across the globe. What the WHO phases do NOT do is predict the severity of the virus.

Using a hurricane analogy, the WHO phase system simply tells us that a hurricane is imminent, but it DOES NOT tell us how big or how strong the storm might be. It is the strength of a hurricane that dictates which pre-landfall actions are needed, such as just boarding up windows versus a full evacuation. While weather forecasters can fly an airplane into the eye of a hurricane to measure a storm's strength and predict its ultimate severity, there is no such forecasting tool for flu viruses.

Does WHO's change to Phase 6 mean the virus is more severe?

No. It is important to understand that this change is based on the geographic spread of the virus to other parts of the world and does not necessarily reflect any change in the severity of the virus or associated illness.

So why did WHO move to Phase 6 if the virus severity is unchanged?

The move to Phase 6 is really an alert that the spread of the H1N1 virus is now expected to traverse the globe and those nations where the virus has yet to arrive should expect to eventually see cases and be prepared to respond.

What does the phase change mean for the United States? What will the U.S. do differently?

Here in the United States, the virus has been spreading steadily from person-to-person since April, so today's announcement by WHO does not really change what we are already doing here at home to respond.

In response to an influenza pandemic, governments, communities, workplaces and individuals will base the intensity of their efforts to reduce spread of the virus on the severity of the disease, as reflected by the number of deaths and hospitalizations from the virus.

The United States has been responding to the H1N1 flu in a way that balances the health of our residents while minimizing disruption to society. We will continue to provide guidance using the most current scientific data available about the H1N1 flu.

Regardless of what WHO calls or labels this, we are taking necessary and aggressive measures to protect the health of our residents out of an abundance of caution.

What actions has the U.S. taken already?

Since the first reports of the appearance of novel H1N1 flu in the U.S., we have been actively and aggressively implementing our pandemic response plan. We have distributed 11 million courses of antiviral drugs nationwide, we have begun the process of procuring a vaccine should it be needed, and we have been routinely providing the latest information to assist health care providers, public health officials and the public in addressing the challenges posed by this newly-identified influenza virus.

Is the outbreak over in the U.S.?

The only thing certain about flu viruses is uncertainty. As we have been saying for some time, we do expect that we will see more cases, more hospitalizations and more deaths from this virus. However, to date most people who have become ill with novel H1N1 in the United States have not become seriously ill and have recovered without hospitalization.

While the number of cases in the U.S. may be waning, we are continuing to prepare for the possibility that the virus may return in the fall. We will continue to watch this virus carefully, especially in the Southern Hemisphere. Every day we learn more about this virus and its impact on human health. As we learn new information, we will adjust our responses and planning, and inform the public and continue to do all we can to make this outbreak less severe.

Is there anything individuals can do?

There are everyday common sense things that people must do to protect their health and lessen the spread of the novel H1N1 virus as well as seasonal flu viruses. Wash your hands and cover your mouth when you cough or sneeze. If you are sick, stay home, recover, and keep others well. Avoid going to work or school. Delay travel plans/. Limit your contact with others. And stay informed—be sure to visit www.hhs.gov, www.cdc.gov, and www.pandemicflu.gov to get the latest information as it becomes available. You can also call 1-800 CDC INFO.

What does Phase 6 mean for vaccine development and production?

First, it is important to recognize that developing a vaccine for use, in case it is needed, is different from recommending individuals be immunized. There is a great deal still unknown, including the severity of illness caused by the virus, how the virus will evolve, how the outbreak plays out in the coming weeks to months, and what populations may be most (or least) at risk.

The process of vaccine preparation is already underway and decisions regarding production will be informed by what we learn about the need for such a vaccine and what we learn about the vaccine itself as it is developed and is used in clinical studies. The goal is to have vaccine(s) ready, if needed, but this is a multi-step process and the decisions to have a vaccine ready, if needed, including, potentially, to produce such vaccines on a large-scale level, is distinct from any decision to recommend its use.

Are you planning an H1N1 immunization program?

While we are all working as fast as possible to develop the vaccine in the event that we need it, please understand that this is separate from a decision to use it, or not. Any decisions on immunization programs must be made on the best scientific and public health evidence available at the time. That said, it is very important that we prepare expeditiously and thoroughly for all potential scenarios.