### **Swine Influenza and You**

#### What is swine flu?

Swine Influenza (swine flu) is a respiratory disease of pigs caused by type A influenza viruses that causes regular outbreaks in pigs. People do not normally get swine flu, but human infections can and do happen. Swine flu viruses have been reported to spread from person-to-person, but in the past, this transmission was limited and not sustained beyond three people.

#### Are there human infections with swine flu in the U.S.?

In late March and early April 2009, cases of human infection with swine influenza A (H1N1) viruses were first reported in Southern California and near San Antonio, Texas. Other U.S. states have reported cases of swine flu infection in humans and cases have been reported internationally as well. An updated case count of confirmed swine flu infections in the United States is kept at <a href="http://www.cdc.gov/swineflu/investigation.htm">http://www.cdc.gov/swineflu/investigation.htm</a> CDC and local and state health agencies are working together to investigate this situation.

### Is this swine flu virus contagious?

CDC has determined that this swine influenza A (H1N1) virus is contagious and is spreading from human to human. However, at this time, it not known how easily the virus spreads between people.

### What are the signs and symptoms of swine flu in people?

The symptoms of swine flu in people are similar to the symptoms of regular human flu and include fever, cough, sore throat, body aches, headache, chills and fatigue. Some people have reported diarrhea and vomiting associated with swine flu. In the past, severe illness (pneumonia and respiratory failure) and deaths have been reported with swine flu infection in people. Like seasonal flu, swine flu may cause a worsening of underlying chronic medical conditions.

### How does swine flu spread?

Spread of this swine influenza A (H1N1) virus is thought to be happening in the same way that seasonal flu spreads. Flu viruses are spread mainly from person to person through coughing or sneezing of people with influenza. Sometimes people may become infected by touching something with flu viruses on it and then touching their mouth or nose.

### How can someone with the flu infect someone else?

Infected people may be able to infect others beginning 1 day before symptoms develop and up to 7 or more days after becoming sick. That means that you may be able to pass on the flu to someone else before you know you are sick, as well as while you are sick.

### What should I do to keep from getting the flu?

First and most important: wash your hands. Try to stay in good general health. Get plenty of sleep, be physically active, manage your stress, drink plenty of fluids, and eat nutritious food. Try not touch surfaces that may be contaminated with the flu virus. Avoid close contact with people who are sick.

#### Are there medicines to treat swine flu?

Yes. CDC recommends the use of oseltamivir or zanamivir for the treatment and/or prevention of infection with these swine influenza viruses. Antiviral drugs are prescription medicines (pills, liquid or an inhaler) that fight against the flu by keeping flu viruses from reproducing in your body. If you get sick, antiviral drugs can make your illness milder and make you feel better faster. They may also prevent serious flu complications. For treatment, antiviral drugs work best if started soon after getting sick (within 2 days of symptoms).

### How long can an infected person spread swine flu to others?

People with swine influenza virus infection should be considered potentially contagious as long as they are symptomatic and possible for up to 7 days following illness onset. Children, especially younger children, might potentially be contagious for longer periods.

### What surfaces are most likely to be sources of contamination?

Germs can be spread when a person touches something that is contaminated with germs and then touches his or her eyes, nose, or mouth. Droplets from a cough or sneeze of an infected person move through the air. Germs can be spread when a person touches respiratory droplets from another person on a surface like a desk and then touches their own eyes, mouth or nose before washing their hands.

### How long can viruses live outside the body?

We know that some viruses and bacteria can live 2 hours or longer on surfaces like cafeteria tables, doorknobs, and desks. Frequent handwashing will help you reduce the chance of getting contamination from these common surfaces.

### What can I do to protect myself from getting sick?

There is no vaccine available right now to protect against swine flu. There are everyday actions that can help prevent the spread of germs that cause respiratory illnesses like influenza. Take these everyday steps to protect your health:

- Cover your nose and mouth with a tissue when you cough or sneeze. Throw the tissue in the trash after you use it.
- Wash your hands often with soap and water, especially after you cough or sneeze. Alcoholbased hand cleaners are also effective.
- Avoid touching your eyes, nose or mouth. Germs spread this way.
- Try to avoid close contact with sick people.
- If you get sick with influenza, CDC recommends that you stay home from work or school and limit contact with others to keep from infecting them.

### What is the best way to keep from spreading the virus through coughing or sneezing?

If you are sick, limit your contact with other people as much as possible. Do not go to work or school if ill. Cover your mouth and nose with a tissue when coughing or sneezing. It may prevent those around you from getting sick. Put your used tissue in the waste basket. Cover your cough or sneeze if you do not have a tissue. Then, clean your hands, and do so every time you cough or sneeze.

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### What is the best technique for washing my hands to avoid getting the flu?

Washing your hands often will help protect you from germs. Wash with soap and water. or clean with alcohol-based hand cleaner. we recommend that when you wash your hands -- with soap and warm water -- that you wash for 15 to 20 seconds. When soap and water are not available, alcohol-based disposable hand wipes or gel sanitizers may be used. You can find them in most supermarkets and drugstores. If using gel, rub your hands until the gel is dry. The gel doesn't need water to work; the alcohol in it kills the germs on your hands.

### What should I do if I get sick?

If you live in areas where swine influenza cases have been identified and become ill with influenza-like symptoms, including fever, body aches, runny nose, sore throat, nausea, or vomiting or diarrhea, you may want to contact their health care provider, particularly if you are worried about your symptoms. Your health care provider will determine whether influenza testing or treatment is needed.

If you are sick, you should stay home and avoid contact with other people as much as possible to keep from spreading your illness to others.

If you become ill and experience any of the following warning signs, seek emergency medical care.

In children emergency warning signs that need urgent medical attention include:

- Fast breathing or trouble breathing
- Bluish skin color
- Not drinking enough fluids
- Not waking up or not interacting
- Being so irritable that the child does not want to be held
- Flu-like symptoms improve but then return with fever and worse cough
- Fever with a rash

In adults, emergency warning signs that need urgent medical attention include:

- Difficulty breathing or shortness of breath
- · Pain or pressure in the chest or abdomen
- Sudden dizziness
- Confusion
- · Severe or persistent vomiting

#### How serious is swine flu infection?

Like seasonal flu, swine flu in humans can vary in severity from mild to severe. Between 2005 until January 2009, 12 human cases of swine flu were detected in the U.S. with no deaths occurring.

However, swine flu infection can be serious. In September 1988, a previously healthy 32-year-old pregnant woman in Wisconsin was hospitalized for pneumonia after being infected with swine flu and died 8 days later. A swine flu outbreak in Fort Dix, New Jerseyoccurred in 1976 that caused more than 200 cases with serious illness in several people and one death.

### Can I get swine influenza from eating or preparing pork?

No. Swine influenza viruses are not spread by food. You cannot get swine influenza from eating pork or pork products. Eating properly handled and cooked pork products is safe

### Vaccines for the new influenza A(H1N1)

2 May 2009

## Is an effective vaccine already available against the new influenza A(H1N1) virus?

No, but work is already under way to develop such a vaccine. Influenza vaccines generally contain a dead or weakened form of a circulating virus. The vaccine prepares the body's immune system to defend against a true infection. For the vaccine to protect as well as possible, the virus in it should match the circulating "wild-type" virus relatively closely. Since this H1N1 virus is new, there is no vaccine currently available made with this particular virus. Making a completely new influenza vaccine can take five to six months.

## What implications does the declaration of a pandemic have on influenza vaccine production?

Declaration by WHO of phase 6 of pandemic alert does not by itself automatically translate into a request for vaccine manufacturers to immediately stop production of seasonal influenza vaccine and to start production of a pandemic vaccine. Since seasonal influenza can also cause severe disease, WHO will take several important considerations such as the epidemiology and the severity of the disease when deciding when to formally make recommendations on this matter. In the meantime, WHO will continue to interact very closely with regulatory and other agencies and influenza vaccine manufacturers.

## How important will influenza A(H1N1) vaccines be for reducing pandemic disease?

Vaccines are one of the most valuable ways to protect people during influenza epidemics and pandemics. Other measures include anti-viral drugs, social distancing and personal hygiene.

## Will currently available seasonal vaccine confer protection against influenza A(H1N1)?

The best scientific evidence available today is incomplete but suggests that seasonal vaccines will confer little or no protection against influenza A(H1N1).

### What is WHO doing to facilitate production of influenza A(H1N1) vaccines?

As soon as the first human cases of new influenza A(H1N1) infection became known to WHO, the WHO Collaborating Center in Atlanta (The Centers for Disease Control and Prevention (CDC) in the United States of America) took immediate action and began the work to develop candidate vaccine viruses. WHO also initiated consultations with vaccine manufacturers worldwide to facilitate the availability of all necessary material to start production of influenza A(H1N1) vaccine. In parallel, WHO is working with national regulatory authorities to ensure that the new influenza A(H1N1) vaccine will meet all safety criteria and be made available as soon as possible.

## Why is WHO not asking vaccine manufacturers to switch production from seasonal vaccine to a influenza A(H1N1) vaccine yet?

WHO has not recommended stopping production of seasonal influenza vaccine because this seasonal influenza causes 3 million to 5 million cases of severe illness each year, and kills from 250 000 to 500 000 people. Continued immunization against seasonal influenza is therefore important. Moreover, stopping seasonal vaccine production immediately would not allow a pandemic vaccine to be made quicker. At this time, WHO is liaising closely with vaccine manufacturers so large-scale vaccine production can start as soon as indicated.

## Is it possible that manufacturers produce both seasonal and pandemic vaccines at the same time?

There are several potential options which must be considered based on all available evidence.

## What is the process for developing a pandemic vaccine? Has a vaccine strain been identified, and if so by whom?

A vaccine for the Influenza A(H1N1) virus will be produced using licensed influenza vaccine processes in which the vaccine viruses are grown either in eggs or cells. Candidate vaccine strains have been identified and prepared by the WHO Collaborating Center in Atlanta (The Centers for Disease Control and Prevention (CDC) in the United States of America)<sup>1</sup>. These strains have now been received by the other WHO Collaborating Centers which have also started preparation of vaccine candidate viruses. Once developed, these strains will be distributed to all interested manufacturers on request. Availability is anticipated by mid-May.

### How quickly will influenza A(H1N1) vaccines be available?

The first doses of Influenza A(H1N1) vaccine could be available in five to six months from identification of the pandemic strain. The regulatory approval will be conducted in parallel with the manufacturing process. Regulatory authorities have put into place expedited processes that do not compromise on the quality and safety of the vaccine. Delays in production could result from poor growth of the virus strain used to make the vaccine.

### How would manufacturers be selected?

There are currently more than a dozen vaccine manufacturers with licenses to produce influenza vaccines. Upon request, the vaccine strain will be available to each of them, as well as to other qualified vaccine manufacturers who are preparing to make influenza vaccine but do not yet have a licensed influenza vaccine.

## What is the global manufacturing capacity for a potential influenza A(H1N1) pandemic vaccine? Is this the same as the global manufacturing capacity for H5N1?

The projections made for the production capacity of an vaccine for H5N1 cannot be automatically assumed to be the capacity to make an H1N1 vaccine. H5N1 and H1N1 viruses are different and the amount of antigen needed to make an effective H1N1 vaccines may be different than for H5N1. Therefore it is not possible to make a precise estimate. However, given these considerations, a conservative estimate of global capacity is at least 1 to 2 billion doses per year.

## How is production capacity for influenza vaccines distributed geographically?

More that 90% of the global capacity today is located in Europe and in North America. However, during the past five years, other regions have begun to acquire the technology to produce influenza vaccines. Six manufacturers in developing countries have done so with technical and financial support from WHO.

### What will be the storage requirements for influenza A(H1N1) vaccine?

The vaccine should be stored under refrigerated conditions at between 2°C and 8°C.

# It has been impossible so far to develop vaccines for major killers such as HIV and malaria. How sure are we that there will not be scientific or other hurdles in developing an effective influenza A(H1N1) vaccine?

Typically, development of influenza vaccines has not posed a problem. Influenza vaccines have been used in humans for many years and are known to be immunogenic and effective. Each year seasonal influenza vaccines with varying composition are produced for the northern and southern hemisphere influenza seasons. Vaccine manufacturers will employ a number of different technologies to develop their vaccines. They will take advantage, notably, of novel approaches that were developed over the past years for H5N1 avian influenza vaccines. One key unknown is yield of vaccine virus production, since some strains grow better than others and the behavior of the new influenza A(H1N1) strain in manufacturers' systems is not yet known. New recombinant technologies are under development, but have not yet been approved for use.

### Will influenza A(H1N1) vaccines be effective in all population

### groups?

There are not data on this but there also is no reason to expect that they would not, given current information.

### Will the influenza A(H1N1) vaccine be safe?

Licensed vaccines are held to a very high standard of safety. All possible precautions will be taken to ensure safety of new influenza A(H1N1) vaccines.

## How can a repeat of the 1976 swine flu vaccine complications (Guillain-Barré syndrome) experienced in the United States of America be avoided?

Guillain-Barré syndrome is an acute disorder of the nervous system. It is observed following a variety of infections, including influenza. Studies suggest that regular seasonal influenza vaccines could be associated with an increased risk of Guillain-Barré syndrome on the order of one to two cases per million vaccinated persons. During the 1976 influenza vaccination campaign, this risk increased to around 10 cases per million vaccinated persons which led to the withdrawal of the vaccine.

Pandemic vaccines will be manufactured according to established standards. However, they are new products so there is an inherent risk that they will cause slightly differently reactions in humans. Close monitoring and investigation of all serious adverse events following administration of vaccine is essential. The systems for monitoring safety are an integral part of the strategies for the implementation of the new pandemic influenza vaccines. Quality control for the production of influenza vaccines has improved substantially since the 1970s.

## Will it be possible to deliver new influenza A(H1N1) vaccine simultaneously with other vaccines?

Inactivated influenza vaccine can be given at the same time as other injectable vaccines, but the vaccines should be administered at different injection sites.

## If the virus causes a mild pandemic in the warmer months and changes into something much more severe in, say, 6 months, will vaccines being developed now be effective?

It is too early to be able to predict changes in the influenza A(H1N1) virus as it continues to circulate in humans or how similar a mutated virus might be to the current virus. Careful surveillance for changes in the influenza A(H1N1) virus is ongoing. This close and constant monitoring will support a quick response should important changes in the virus be detected.

### Will there be enough influenza A(H1N1) vaccine for everyone?

The estimated time to make enough vaccine to vaccinate the world's population against pandemic influenza will not be known until vaccine manufacturers will have been able to determine how much

active ingredient (antigen) is needed to make one dose of effective influenza A(H1N1) vaccine.

In the past two years, influenza vaccine production capacity has increased sharply due to expansion of production facilities as well as advances in research, including the discovery and use of adjuvants. Adjuvants are substances added to a vaccine to make it more effective, thus conserving the active ingredient (antigen).

## What is WHO's perspective on fairness and equity for vaccine availability?

The WHO Director-General has called for international solidarity in the response to the current situation. WHO regards the goal of ensuring fair and equitable access by all countries to response measures to be among the highest priorities. WHO is working very closely with partners including the vaccine manufacturing industry on this.

## Who is likely to receive priority for vaccination with a future pandemic vaccine?

This decision is made by national authorities. As guidance, WHO will be tracking the evolution of the pandemic in real-time and making its findings public. As information becomes available, it may be possible to better define high-risk groups and to target vaccination for those groups, thus ensuring that limited supplies are used to greatest effect.

## Will WHO be conducting mass influenza A(H1N1) vaccination campaigns?

No. National authorities will implement vaccination campaigns according to their national pandemic preparedness plans. WHO is exploring whether the vaccine can be packaged, for example, in multidose vials, to facilitate the rapid and efficient vaccination of large numbers of people.

Developing countries are very experienced in administering population-wide vaccination campaigns during public health emergencies caused by infectious diseases, including diseases like epidemic meningitis and yellow fever, as well as for polio eradication and measles control programmes.

## How feasible will it be to immunize large numbers of people in developing countries against a pandemic virus?

Developing countries have considerable strategic and practical experience in delivering vaccines in mass campaigns. The main issue is not feasibility, but how to ensure timely access to adequate quantities of vaccine.

## What is the estimated global number of doses of seasonal vaccine used annually?

The current annual demand is for less than 500 million doses per year.

### Will seasonal influenza vaccine continue to be available?

At this time there is no recommendation to stop production of seasonal influenza vaccine.

<sup>1</sup>National Institute for Biological Standards and Control (UK), Food and Drug Administration/Center for Biologics Evaluation and Research (USA), New York Medical College (USA), Victorian Infectious Diseases Research Laboratory (Australia)