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Answers to Your H1N1 Vaccine Clinical Research Trial Questions

About H1N1

Q. What is Influenza A (H1N1)?

A. Novel influenza A (H1N1) – previously referred to as “swine flu” – is a new influenza virus that was first detected in humans in April 2009 in Mexico and the U.S. Since then, the virus has been detected in more than 70 countries. The fast spread of the virus led the World Health Organization (WHO) to raise the pandemic alert level to Phase 6, making it the first influenza pandemic declared in more than 40 years.

Q. What is a pandemic?

A. A pandemic is a global disease outbreak. A flu pandemic occurs when a new influenza virus for which people have little or no immunity emerges and spreads rapidly. Because there is little or no pre-existing natural immunity – or protection – to these viruses, there is a risk that pandemic flu may lead to higher rates of severe illness and death than seasonal influenza (although it is not now known how severe the virus will be). Seasonal influenza is associated with approximately 36,000 deaths per year in the United States alone, mostly in individuals with chronic disease or elderly.

Q. Is the new H1N1 flu different than swine flu?

A. Influenza H1N1 was referred to early on as “swine flu” because it was originally thought that the new virus was similar to flu viruses that normally occur in pigs in North America. Further study showed that the virus contained

genes from flu viruses found in pigs in Europe and Asia, as well as avian and human genes, so the virus was renamed H1N1.

Q. In general, should I be concerned about swine flu?

A. People usually get swine flu from infected pigs; however, human-to-human transmission has occurred in some instances. If a swine virus establishes efficient human-to-human transmission, it can cause an influenza pandemic.

In the case of the new H1N1 virus, part of the virus is of swine origin; however it has been mixed with other virus genes, so it is not a classic example of swine flu infection.

Q. Is the new H1N1 flu contagious?

A. The U.S. Centers for Disease Control and Prevention has determined that H1N1 is contagious and is spreading from human to human. At this time, it is not known how easily the virus spreads between people.

Q. How is the new H1N1 virus spread?

A. It is believed that the new H1N1 virus is spread in the same way that seasonal flu spreads. Flu viruses travel from person to person through coughing or sneezing. Sometimes, people may become infected by touching something with flu viruses on it and then touching their mouth or nose.

The new H1N1 virus is not spread by eating food, such as pork or pork products, and cannot be spread through water in public swimming pools.

Q. What are the symptoms of the new H1N1 flu?

A. The symptoms of the new H1N1 flu are similar to the symptoms of seasonal flu and include fever, cough, sore throat, runny or stuffy nose, body aches, headache, chills and fatigue. Unlike traditional seasonal flu, a significant number of people who have been infected with the H1N1 virus also have reported diarrhea and vomiting.

Q. How is the new H1N1 flu different from seasonal flu?

A. Seasonal influenza is a contagious respiratory illness that is also caused by flu viruses. Flu viruses are constantly changing, which requires people to receive a new seasonal flu vaccine each year. Most people, though, have been exposed to flu viruses in the past and have developed some immunity – or protection – against seasonal flu.

Pandemic influenza, by contrast, is caused by a new strain of flu virus that appears in people, causing a global outbreak – or pandemic – of influenza illness. Few people have immunity to a pandemic virus, and in most cases, available influenza vaccines against seasonal flu viruses do not provide protection against a new pandemic virus. A new vaccine must be developed, which is specifically targeted against the new pandemic virus.

Q. How dangerous is the new H1N1 flu?

A. It is not known how severe the new H1N1 flu could be in the general population. To date, the largest number of confirmed and probable cases of

new H1N1 pandemic flu to date have occurred in people between 5 and 24 years of age.

Because there is little or no pre-existing natural immunity – or protection – to these viruses, there is a risk that pandemic flu may lead to higher rates of severe illness and death than seasonal influenza (although it is not now known how severe the virus will be). Seasonal influenza is associated with approximately 36,000 deaths per year in the United States alone, mostly in individuals with chronic disease or elderly.

The deadliest pandemic was in 1918 and resulted in as many as 50 million deaths worldwide.

Q. Who is most at risk from the new H1N1 flu?

A. Currently, it is still too early to fully characterize who is at risk from the new H1N1 virus; however, the largest number of confirmed and probable cases of new H1N1 pandemic flu to date have occurred in people between 5 and 24 years of age.

With seasonal flu, certain people are at higher risk of serious flu-related complications. This includes people 65 years of age and older, children younger than 5 years of age, pregnant women and people with certain chronic medical conditions. As has been shown with seasonal flu, pregnancy and other medical conditions, such as asthma and diabetes, appear to be associated with increased risk of complications from H1N1 infection.

Early reports from studies conducted by the U.S. Centers for Disease Control and Prevention (CDC) indicate that as many as one-third of people 60 years of age and older have immunity to the new H1N1 virus. However, no children and few adults younger than 60 years of age have any existing immunity.

It is unknown if this immunity will be enough protect people against the current pandemic.

H1N1 Vaccine

Q. Why does a person need a vaccine against the new H1N1 virus?

A. Similar to seasonal flu, the most effective way to help protect oneself from a pandemic flu virus and limit spread of the disease may be through a comprehensive vaccination program, which is specifically targeted against the new pandemic virus. Experience with seasonal flu has already shown that vaccination is the most effective public health intervention ever implemented, sparing millions of people from complications of the infectious disease. Use of currently available seasonal flu vaccines has been calculated to save more than 8 million lives annually, translating to one person saved every five seconds.

Q. What does a vaccine against the new H1N1 do?

A. The purpose of H1N1 vaccination is to prime the immune system to better defend against infections from the new H1N1 virus. When properly primed, the body is able to develop a protective immune response against an infection faster and help ward off serious flu-related complications.

Q. Does a new H1N1 vaccine currently exist?

A. A vaccine does not currently exist to protect people against the new H1N1 virus, but vaccine manufacturers are working with the CDC and the World Health Organization to develop a vaccine to protect against the current pandemic and the potentially life-threatening consequences of the illness.

If current clinical research trials evaluating investigational H1N1 vaccines are successful, a vaccine could be available this Fall/Winter.

Q. Will a seasonal flu vaccine protect me against the new H1N1 flu?

A. Neither the World Health Organization (WHO) nor the CDC believe that a seasonal flu vaccine will provide

protection against the new H1N1 flu. A new vaccine must be developed to specifically target the new pandemic virus.

Q. It seems that fewer people are getting sick. If the new H1N1 virus is going away, do I still need a vaccination?

A. News reports of the new H1N1 flu have decreased, but the actual incidence rates of influenza like illness have not gone down. And, while experts expect transmission of H1N1 virus to decrease during the summer, many people believe that incidence rates will increase again in the fall and winter.

The deadliest pandemic, which started in 1918 and resulted in as many as 50 million deaths worldwide, began in the spring and spread in three distinct waves. The second wave, which began in the winter of 1918, was the deadliest of the three.

H1N1 Clinical Research Trials

Q. What are clinical research trials?

A. A clinical research trial is a research study to answer specific questions about vaccines, new investigational therapies or new ways of using known treatments. Clinical research trials are used to determine whether new drugs or treatments are both safe and effective, and are required by the government for licensure of all treatments and vaccines for use in people.

Q. Who is eligible to participate in these H1N1 vaccine clinical research trials?

A. There are two clinical research trials being conducted with an investigational vaccine – one for children 3 to 8 years of age and one for adults 18 years of age and older, including seniors 65 years of age and older.

The clinical research trial is open to people who:

- Are healthy
- Have not had the flu in the last 6 months

- Have not received a seasonal flu vaccine in the week prior to the clinical research study vaccination
- Will not receive a seasonal flu vaccine in the week after the clinical research study vaccination

Q. Why should a parent or guardian consider enrolling their child in a clinical research trial?

A. One of the benefits of clinical research trials is helping others by contributing to medical research. Information collected from this clinical research trial will be necessary to ensure that this vaccine is available in the U.S. this Fall/Winter.

In addition, any one enrolled in the clinical research trial will receive the investigational H1N1 vaccine at no charge.

Q. Will the investigational vaccine that participants receive in the clinical research trial be enough to protect them against the new H1N1 flu?

A. This is not yet known, but it is one of the questions being addressed by the clinical research trial. Vaccines are composed of antigens, which are proteins that bring about a protective immune response in the body. Part of what we are trying to determine is how much antigen needs to be in each vaccine in order for the body to develop a protective immune response.

In addition, some clinical research trial participants will receive H1N1 vaccine in which an adjuvant has been added. Adjuvants are substances that are added to vaccines to help stimulate the body's immune response. One purpose of the clinical research trial is to determine how different amounts of an adjuvant might enhance the development of a protective immune response.

Until we have complete data, we cannot anticipate how people might respond to the vaccination.

Q. How long will the clinical research trial take?

A. Qualified participants will be asked to complete five clinic visits. In addition, participants will be followed for approximately 13 months to evaluate the long-term safety of the vaccine.

Q. Is the new H1N1 vaccine safe?

A. The investigational H1N1 vaccine that is being tested in this clinical research trial is similar to a seasonal influenza vaccine, which is licensed for use in the U.S. The licensed vaccine is generally well tolerated, and the most common side effect of vaccination is soreness at the injection site. Less common side effects include fever, malaise, muscle pain, allergic reactions, egg hypersensitivity and anaphylaxis.

General Considerations Before Participating in a Clinical Research Trial

Q. What are the benefits and risks of participating in a clinical research trial?

A. Benefits:

Clinical research trials that are well-designed and well-executed provide an opportunity for eligible participants to:

- Play an active role in their own health care.
- Help others by contributing to medical research

Risks:

All clinical research trials involve some level of risk that must be weighed before people agree to participate or parents agree to let their children participate. Risks can include:

- Whereas most flu vaccines are well-tolerated, there is the possibility that a participant could experience symptoms, such as pain at the injection site, sleepiness, irritability or a rash.

- The treatment may not be effective for the participant.
- The protocol may require more time and attention than a non-protocol treatment, including trips to the clinical research study site and more treatments

Q. Could the new H1N1 vaccine cause a person to get the flu?

A. Contrary to popular belief, it is not possible to get flu from a flu vaccine. This is true for the seasonal flu vaccine, as well as the investigational H1N1 vaccine.

Q. Do vaccines cause autism?

A. No. Numerous scientific studies have found no evidence of a causal link between vaccines and autism. According to the CDC, overwhelming evidence indicates that vaccines, including those that contain Thimerosal (a preservative contained in some vaccines), are not associated with autism. Recently, Special Masters (judges) in three vaccine courts set up by the U.S. government heard cases brought by parents of autistic children on the grounds that vaccination caused or contributed to their children's autism. After reviews of extensive scientific data entered by both sides, the Special Masters concluded independently that there is no evidence that vaccines contribute in any way to the onset of autism.

Q. Is there Thimerosal in this investigational vaccine?

A. The vaccine contains Thimerosal.

Q. What is Thimerosal?

A. Thimerosal is a preservative that is used in multi-dose vaccine vials to help ensure the safety of the vaccine by preventing bacteria and fungal contamination during the multiple needle sticks when vaccine is withdrawn from the vial.

For More Information

For more information on how to participate in the clinical research trial to evaluate the investigational H1N1 vaccine, please call (303) 773-9000 or (877) 8-IMMUNE.