



Facts and Myths about the Safety of the Pandemic Influenza (H1N1) 2009 Vaccine

1. Is the influenza pandemic real?

- **Yes, it's a real pandemic.** To date, it has caused the death of over **17,000 people**, despite a rapid reaction from public health authorities. This is not the final figure, as the full magnitude of the pandemic's impact in terms of people infected and killed is yet to be determined.
- This is a novel influenza virus that spread worldwide in just a few weeks. The belief that the influenza (H1N1) pandemic is a hoax is scientifically mistaken and historically incorrect.

2. Did the World Health Organization exaggerate the pandemic?

- **No, WHO did not exaggerate.** We have always known that pandemics can range in severity from mild to severe and can even undergo a change in severity as they run their course. WHO and other responsible health authorities have adopted a preventive approach—that is, preparing for the worst-case scenario in order to save lives. Better to prevent than regret.
- In making this decision, WHO consulted independent world experts through Advisory Committees. WHO is constantly verifying that the experts who sit on its Advisory Committees have no conflicts of interest that could influence their technical opinion.
- So far, the health impact of this pandemic, compared to that of past pandemics, has been moderate. Countries have found means and have taken actions that were critical to reducing the severity of the pandemic.

3. Why has pandemic influenza (H1N1) 2009 generated so much concern when thousands of people die each year due to seasonal flu?

- **The 2009 (H1N1) virus, the cause of the current pandemic, is a novel virus,** against which most people have very little or no protection. As a result, it has the potential to cause more infections and deaths than the seasonal flu.
- Seasonal influenza occurs every year, and although viruses mutate annually, many people have a certain amount of protection against these viruses, which helps limit infection. Furthermore, many countries already vaccinate against seasonal flu in order to reduce the number of people who will contract influenza or die from it.

This is not the case with the pandemic (H1N1) 2009 virus; hence, more stringent precautions are being taken.

4. Which type of pandemic influenza vaccine is used in Latin America and the Caribbean?

- Broadly speaking, there are two types of pandemic influenza vaccine: the inactivated vaccine and the attenuated vaccine.
- The vaccine that is administered in Latin America and the Caribbean is an inactivated vaccine, made from killed virus particles. As a result, this vaccine cannot cause influenza. Thus, this type of vaccine is indicated for pregnant women and people with chronic diseases, including those with immunodeficiencies (weakened immune defenses). This vaccine is administered as an injection.
- The attenuated vaccine, which contains live viruses, should not be used in pregnant women or the aforementioned groups. In the Americas, the attenuated pandemic influenza vaccine is available only in the United States and Canada, and is administered through a nasal spray (into the nose).

5. Does the pandemic influenza vaccine really confer protection?

- **Yes, these vaccines have proven to be effective** in producing defenses against infection with pandemic influenza (H1N1), which means that their administration is very important in high-risk groups: health workers, pregnant women, and people living with chronic diseases.
- It is important that health workers be vaccinated to keep the health system up and running and prevent them from infecting people who already have other diseases.
- It is important that pregnant women and people with chronic diseases be vaccinated because they are at a greater risk of complications and death from pandemic influenza.

6. Is the pandemic influenza (H1N1) 2009 vaccine safe?

- **The vaccine is safe.** As of early May, more than 400 million doses of pandemic influenza (H1N1) vaccine had been administered worldwide. In the Americas alone, over 70 million doses have been administered in 23 countries in Latin America and the Caribbean, and between the United States (127 million) and Canada (24 million), 151 million doses have been provided to health workers, high-risk groups, and the general population. Not a single adverse event that would call the safety of the vaccine into question has been confirmed to date.
- One of the concerns of national governments, their authorities, the population, and international health organizations is ensuring the safety of the vaccine. For this reason, adverse event reporting has been strengthened and complemented by exhaustive investigations to scientifically determine whether any events that occur are a coincidence or are indeed due to vaccination. This is proof of responsible management and of looking out for the interests and well-being of the population.
- To date, there have been reports of a limited number of possible events supposedly attributable to vaccination that have jeopardized the health of vaccinated people (severe events). A thorough scientific investigation of these events is under way to

ascertain whether they were really caused by the influenza vaccine. This investigation is being conducted by the ministries of health of the countries where they have been reported.

- The adverse events reported with this vaccine are quite similar to those seen with the seasonal flu vaccine—that is, local reaction, pain at the injection site, headache, and malaise may occur. The symptoms subside after 48 hours.
- The seasonal flu vaccine is a very safe vaccine that is administered every year to millions of people, without any evidence that it causes permanent injury or death in vaccinated people; on the contrary, it protects them from influenza. Vaccines are developed to save lives.

7. Has production of this vaccine been different from that of the seasonal influenza vaccine?

- **No, the process and quality standards used in the manufacture of pandemic influenza (H1N1) vaccine and seasonal influenza vaccine are the same.** Although all possible measures have been taken to speed up production of the pandemic influenza vaccine, the same manufacturing protocols used for seasonal influenza vaccine have been followed, due to the concern on the part of manufacturing laboratories, governments, and the general public about ensuring the safety of the pandemic influenza (H1N1) vaccine. The time required to manufacture the new pandemic influenza vaccine (4 to 6 months) has remained similar to that of the seasonal influenza vaccine (6 months) precisely because of these precautions.

8. Is this vaccine safe for pregnant women?

- **Yes, it is safe for pregnant women.** To date, not a single adverse event has been observed that has endangered vaccinated pregnant women or their unborn children compared with unvaccinated pregnant women.
- Furthermore, approximately 1 out of every 10 deaths from pandemic influenza (H1N1) has been found to occur in pregnant women.
- For this reason, the **vaccination of pregnant women is highly recommended.** Vaccination will help to avoid the high risk of infection with and complications from pandemic influenza that can lead to miscarriage and death of the mother and baby, particularly in the second and third trimesters of pregnancy and in the two weeks after delivery.

9. Which reactions may occur if my child and I get the vaccine?

- **The usual and expected side effects.** The most commonly reported discomfort following vaccination against pandemic influenza (H1N1) have been swelling and pain at the injection site, malaise, headache, irritability, and/or fever. These symptoms usually do not require medical attention and may persist for 1 or 2 days.
- Bear in mind that other symptoms that may occur soon after vaccination are not necessarily due to the vaccine. In case of doubt, the best course of action is to return to the place where you were vaccinated or see a physician of your choice.

10. Does pandemic influenza vaccine contain any substances that can cause death or sequelae in the short or long term?

- **No, the vaccines do not contain any substances that are particularly toxic.** Quite the contrary, they contain substances that prevent vaccine contamination and boost its capacity to produce defenses in the body.
- Severe adverse reactions to vaccines are exceedingly rare. To date, hundreds of millions of doses have been administered without a single confirmed case of death or disability caused by the vaccine itself.

11. Does the pandemic influenza vaccine contain mercury?

- This vaccine does NOT contain mercury, which has proven to be toxic. What is used is a substance known as thimerosal (also known as thiomersal) that is easily cleared from the body. The organic properties of thimerosal make it non-toxic, even though it is a mercury derivative. Thimerosal is particularly necessary in multidose vaccines (those in which a single vial is used to immunize several people), to avoid environmental contamination of the vaccine between administrations. Thus, not only is thimerosal non-toxic, it also benefits people by allowing the vaccine they will receive to be kept under adequate conditions, thereby ensuring its safety.

12. Can thimerosal cause autism?

- **No.** The vast number of studies conducted have been unable to find a causal relationship between thimerosal and autism. In fact, in some countries that removed this substance from nearly all vaccines used in their immunization programs in an attempt to reduce autism rates in children, the measure was unsuccessful. In these countries, the number of children with autism, instead of falling, has continued to rise, even though the vaccines they use no longer contain thimerosal. Therefore, as this hypothesis has been ruled out, special efforts continue to be made to try to discover the causes of autism.

13. What is the effect of the adjuvants contained in the vaccine?

- Some pandemic influenza vaccines contain an adjuvant to help the body create defenses against influenza. The adjuvants used in this vaccine contain squalene. Squalene has been used in seasonal influenza vaccines in Europe for over 10 years with an excellent safety record. Squalene is a substance that occurs naturally in plants, animals, and even in our own body. It is essential for our survival and is actually found in many foods. Squalene is produced in the liver and can be found in the fingerprints we leave on everything we touch.

14. Can squalene cause Guillain-Barré syndrome (GBS)?

- **No.** Guillain-Barré syndrome is a disease that causes muscular paralysis and can have multiple causes. Viral infection is believed to be one of these causes.
- During the Gulf War, a vaccine against anthrax (a disease caused by bacteria, not a virus) was administered to U.S. troops, some of whom subsequently developed GBS. It was thought that squalene could have played a role, but this has been completely ruled out through scientific research. In fact, studies concluded that the cases of GBS bore no relation to anthrax vaccination or squalene. Four panels of civilian scientists have reviewed the findings of these studies and confirmed their results.

15. Can the influenza vaccine cause Guillain-Barré syndrome?

- In the 1970s, an increase in the number of GBS cases was detected in a group of military personnel who had been vaccinated against a novel type of influenza. Later, exhaustive studies could not pinpoint the cause of this increase that may have been due to a number of circumstances.
- Over the four ensuing decades, the vaccine production process has been greatly improved to ensure that the population receives an increasingly safe product. In fact, a situation like the one mentioned above has not arisen with any other influenza vaccine. Furthermore, surveillance has been enhanced in order to identify and investigate every suspect vaccine-related adverse event.

16. If this vaccine is safe, why are there reports and investigations?

- Precisely because the monitoring of vaccine safety entails a thorough investigation of every case in which the vaccine is suspected to have caused an adverse reaction, particularly a severe one.
- Not only is thorough monitoring and investigation of reported adverse events proof of how responsibly the process is handled, it also allows us to reaffirm that the vaccine is safe.

17. What influence does the pharmaceutical industry have over the World Health Organization (WHO)?

- **None. WHO always puts the interests of global public health** above any other financial or corporate interest.
- To this end, it has always provided clear, scientific, evidence-based information and taken particular care to avoid any conflict of interest among its personnel and its body of advisers.
- WHO requires that experts who advise the organization disclose any potential conflict of interest. This information is shared and verified to ascertain whether each expert can continue to offer advisory services to the organization.
- WHO monitors and certifies vaccine quality and good manufacturing practices.

18. Do donated vaccines come from surplus vaccines not used in other countries because they are ineffective or faulty?

- It is not true that vaccines are donated because they were not effective, or that donations come from faulty vaccines rejected by the government or population. The truth is that countries with limited resources cannot procure all the vaccine that they need and require support to obtain them to protect their citizens. WHO has stressed this point since the onset of the pandemic. Thus, it negotiated vaccine donations with manufacturing laboratories and developed countries to ensure that countries with fewer resources could vaccinate at least 10% of their population. This is the estimated percentage of people who make up the three major priority groups for the reduction of complications and deaths from novel influenza: 1) health workers, 2) pregnant women, and 3) people with chronic diseases.