

The European Scientific Working group on

INFLUENZA

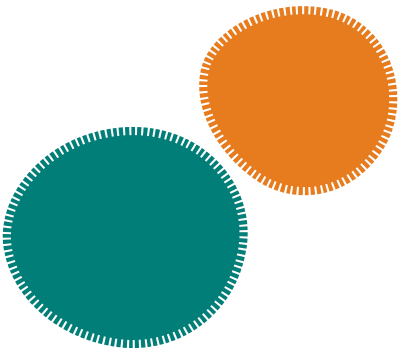
The outbreak of the Mexican influenza A (H1N1) virus was declared a pandemic by the World Health Organization (WHO) on 11 June 2009. More than half a year later, the impact of the pandemic is at the low end of what had been expected and it can only be hoped that this moderate impact will continue throughout the duration of the pandemic.

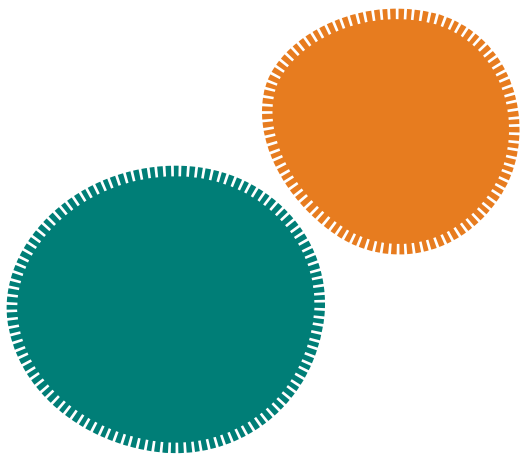
However, influenza viruses are notoriously unpredictable, and the mere fact that the virus may change to a more pathogenic virus in the future calls for a continuous state of alert and the implementation of appropriate pandemic preparedness measures, on various levels. One of the basic medical components of an adequate pandemic preparedness plan is the use of a pandemic vaccine to protect health risk groups, once such a vaccine becomes available. To put it differently, ensuring maximal vaccination coverage of prioritized groups is key to mitigating the impact of a pandemic. The benefits of the timely availability of a pandemic vaccine are neutralized if prioritized groups do not get the vaccine.

Clear messages about the importance, the safety and the efficacy of the pandemic vaccines are key to convince prioritized groups to take the vaccine. Here is an overview of the most commonly asked questions about vaccine safety and efficacy...

ESWI's Third Pandemic Preparedness Workshop for Public Health Officials was held in Brussels on 22 January 2010.

Please visit www.eswiworkshop.org for the minutes of the meeting.





1. Have the pandemic vaccines been sufficiently tested for safety and efficacy?

Evidently, registration authorities faced their own challenges when WHO declared the pandemic. Although there were guidelines in place for the registration of new influenza vaccines, the investments as well as the time required to fulfil these criteria would be a registration barrier for quick access in the event of a public health crisis. Therefore, registration authorities developed guidelines, which sought a careful balance between registration requirements for pandemic vaccines and timely availability. In Europe, the “mock-up dossier” procedure was introduced.

The first mock-up files for H5N1 prototype pandemic vaccines were approved by the European Agency for the Evaluation of Medicinal Products (EMA) in 2007. One of the seasonal adjuvanted vaccines was already administered to millions of people with no safety issues observed. The registration of the mock-up vaccine, including the results of preclinical and clinical tests would allow a rapid dossier evaluation when a pandemic virus strain would emerge for which a true pandemic vaccine was to be made, as was the case for the current H1N1 virus. In addition to the data presented in the mock-up dossier, the registration requirements for a true pandemic vaccine included post licensure studies and an intense pharmacovigilance programme to monitor safety and efficacy.

In conclusion we could say that approved vaccines - including the currently available pandemic flu vaccines - are safety tested and no observations were made to suggest any safety concern.

2.

Are adjuvanted vaccines really safe?

Some pandemic vaccines contain so called adjuvants, substances that stimulate the immune system and increase the response to a vaccine, without having a specific antigenic effect themselves. The advantages, certainly in a pandemic situation, are obvious: adjuvants improve the immune response whilst the viral antigen dose size can be decreased. The latter is an excellent way to increase global vaccine manufacturing capacity.

Two types of adjuvants are included in the pandemic vaccines: alum-based and squalene-based. Alum-based adjuvants have been used in many different vaccines for the past 60 years and, therefore, the clinical experience is vast. Squalene-based adjuvants have been introduced more recently, but they have been used in seasonal influenza vaccines provided to older people since 1997. It is estimated that more than 45 million doses have been distributed in Europe. Squalene is a naturally occurring substance found in plants, animals, and humans. It is commercially extracted from fish oil and shark liver.

On 19 November 2009, WHO has issued a safety report on H1N1 vaccines used in 16 countries in which, at that time, 65 million people were vaccinated. No specific adverse event observations gave rise to any particular safety concern. An intense pharmacovigilance surveillance programme is on-going (www.who.int/csr/disease/swineflu/notes/briefing_20091119/en/print.html).

3.

Have pandemic vaccines been proven to be effective against the H1N1 Mexican flu virus?

The first clinical studies with H1N1 pandemic vaccines show a very promising picture. In contrast to H5N1 vaccine, it seems that immunization with one single antigenic dose provides already an adequate seroresponse in each of the tested and approved H1N1 pandemic vaccine formulations. This is good news for the total global vaccine production capacity, but still there will not be enough pandemic vaccine for the whole world population. Hence, prioritizing risk groups is key.



4.

Who should be vaccinated first against pandemic influenza?

HEALTH CARE WORKERS

The WHO has recommended that Health Care Workers (HCW) are on the priority list of people to be vaccinated with the H1N1 vaccine (WHO Strategic Advisory Group of Experts (SAGE), July 2009). This advice was given for all countries. SAGE has listed priority groups for immunization but advised countries to develop their own priority list in light of national vaccine availability. HCW should also do their best to advertise vaccination among their patients, with special reference to the most vulnerable ones.

PREGNANT WOMEN

Pregnant women should be immunized against the pandemic flu strain, preferably in the third trimester of their pregnancy, since the risk of severe complications is greatest in that trimester, 3-5 times higher than for non-pregnant women.

Those with chronic medical conditions
Such as:

- Chronic pulmonary disease, including asthma
- Cardiovascular disease
- Chronic renal insufficiency
- Diabetes
- Severe obesity (BMI >35)

HEALTHY CHILDREN

Children under five years old are at an increased risk of contracting the H1N1 virus. Vaccination is currently not recommended for children below 6 months of age, however relatives in close contact with the infected should be immunised.

HEALTHY ADULTS



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