

Vaccines for pandemic influenza A(H1N1)

Up-to-date as of 12 July 2009 (Originally posted on 2 May 2009 and revised on 27 May 2009)

1. Production and availability of pandemic influenza A(H1N1) vaccines:

Is a vaccine against pandemic influenza A(H1N1) virus available to immunize people?

No, but work is well under way to develop such a vaccine. Making new influenza vaccines ready to immunize people generally takes five to six months after first identification of the pandemic virus. The pandemic influenza A(H1N1) 2009 virus was identified at the end of April 2009.

How quickly will pandemic influenza A(H1N1) vaccines be available for use?

The very first doses of influenza A(H1N1) vaccine usable to immunize people, from one or more manufacturers, are expected as early as September 2009.

What implications does the declaration of a pandemic (phase 6) have on influenza vaccine production?

When the WHO Director-General declared the influenza A(H1N1) pandemic on 11 June 2009, she noted that production of seasonal influenza vaccines would be completed soon and that full industrial production capacity would then be available to ensure the largest possible supply of pandemic vaccine in the months to come.

Which manufacturers will make pandemic influenza A(H1N1) vaccines?

There are currently around twenty vaccine manufacturers with licenses to produce seasonal influenza vaccines. There are other qualified vaccine manufacturers who are preparing to make influenza A(H1N1) vaccine, but do not yet have a licensed seasonal influenza vaccine.

What is the global manufacturing capacity for a potential influenza A(H1N1) pandemic vaccine?

Based on a global survey made by WHO on 15 May 2009, a maximum of 4.9 billion doses potentially could be produced in 12 months, but only if several assumptions are met. First, full global manufacturing capacity is devoted to this production. Second, production yields for influenza A(H1N1) vaccine are similar to those usually obtained for seasonal vaccines. Third, each manufacturer uses the vaccine formulation that is most "dose-sparing" (i.e., using a smaller quantity of active principle). A more conservative estimate of global capacity is at least 1 to 2 billion doses per year. The numbers of persons who might be vaccinated will not be known until it is determined whether one or two doses of the vaccine will be needed to achieve protection.

What technologies will be used to grow pandemic influenza A(H1N1) viruses to make vaccines?

Most of these vaccines will be produced using chicken eggs, while a few manufacturers are using cell culture technology for vaccine production.

How is the production capacity for influenza vaccines distributed geographically?

Around 70% of the global seasonal influenza vaccine production capacity today is located in Europe and North America, with further significant manufacturing capacity in Australia, Japan, and China. During the past three years, six manufacturers in developing countries have begun to acquire the technology to produce influenza vaccines and have received technical and financial support from WHO. Since May 2009, five additional new producers have joined this initiative.

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

When pandemic vaccine first becomes available, it is anticipated that the demand will be greater than the supply. This gap will narrow as more vaccine becomes available over time.

Who will receive priority for vaccination?

WHO is working with the Strategic Advisory Group of Experts (SAGE) on immunization and partners on the options for deciding in which target groups vaccination should begin first. At its July 7 meeting, SAGE recommended that health care workers worldwide should be immunized as a first priority (see *Pandemic (H1N1) 2009 briefing note 2* available at http://www.who.int/csr/disease/swineflu/notes/h1n1_vaccine_20090713/en/index.html). Ultimately, national authorities will identify priority groups for vaccination based on circumstances within the country.

Will developing countries have access to pandemic influenza vaccines?

The WHO Director-General has called for international solidarity to provide fair and equitable access for all countries to pandemic vaccine when it becomes available. WHO has requested that manufacturers set aside future influenza A(H1N1) vaccines for developing country populations, through donations or affordable pricing arrangements.

2. Safety and approval of pandemic influenza A(H1N1) vaccines

Will new pandemic influenza A(H1N1) vaccines be safe?

Licensed vaccines, including influenza vaccines, are held to a very high standard of safety. Likewise, all possible precautions will be taken to ensure safety of new pandemic vaccines and results from clinical trials, currently ongoing or soon to be initiated, will be taken into consideration by the regulatory authorities in their decision to license pandemic vaccines. In early June, WHO held a consultation of experts which reviewed the safety of adjuvants, or substances added to vaccines to make them more effective; no significant safety concerns were identified. Vaccine safety will be carefully monitored through post-marketing surveillance.

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 (GBS) is an acute disorder of the nervous system. It sometimes develops following a variety of infections, including influenza. Studies suggest that seasonal influenza vaccines could sometimes 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, about 10 persons per million vaccinated

persons developed GBS which stopped the vaccination campaign and led to the withdrawal of the vaccine.

The reason why GBS developed in association with that specific vaccine has never been firmly established. The potential for the development of a similar risk with future vaccines can never be firmly excluded. However, the influenza A(H1N1) vaccine will be manufactured according to established standards and post-marketing surveillance will be conducted to monitor potential development of any serious adverse events following administration of vaccine. Safety monitoring systems are an integral part of strategies for the implementation of the new pandemic influenza vaccines.

Who will approve (license) new influenza A(H1N1) vaccines for use?

Regulatory approval for new influenza A(H1N1) vaccines will be conducted by national authorities. National regulatory authorities have put into place expedited processes that do not compromise on the quality and safety of the vaccine.

3. Use of pandemic influenza A(H1N1) vaccines:

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

Inactivated influenza vaccine can be given at the same time as other injectable non-influenza vaccines, but the vaccines should be administered at different injection sites. Advice is being developed at present by regulatory authorities on co-administration of pandemic and seasonal influenza vaccines and will be provided when available.

How can a person who wishes to be vaccinated against influenza A(H1N1) receive the vaccine?

Once the first doses of pandemic influenza A(H1N1) vaccine become available, national health authorities will decide how to implement national vaccination campaigns.

4. Seasonal influenza vaccines:

Will current seasonal influenza vaccines offer any protection against influenza A(H1N1) infection?

So far, evidence suggests that it is unlikely that seasonal influenza vaccines will be protective against the new pandemic virus.

When is production of seasonal influenza vaccine likely to be completed?

More than 90% of seasonal influenza vaccine production for the Northern Hemisphere (2009-10) is expected to be completed by the end of July. Analysis of epidemiological evidence available in September 2009 will be critical to determine the composition of the Southern Hemisphere's 2010-11 seasonal influenza vaccine, and how much vaccine will be needed.

Should people continue to be vaccinated against seasonal influenza?

When it met on 7 July 2009, SAGE did not propose changes to the current WHO seasonal vaccination recommendations. People should therefore continue to seek seasonal influenza vaccination like any other year.