

10 Q&A about H1N1 vaccines

1. Why is vaccination against H1N1 influenza necessary?

Vaccination is one of the most effective and safe ways to prevent people from contracting illness during influenza pandemics. The WHO's Strategic Advisory Group of Experts on Immunization (SAGE) as well as the European Health Security Committee have recommended vaccination against H1N1 influenza, based on local priorities and capabilities.¹

When deciding whether to offer vaccinations against H1N1 pandemic influenza, health authorities will consider scientific advice as well as local conditions.

2. Which groups should be vaccinated first?

Health authorities will decide the priority groups for immunization based on local conditions as well as broader scientific recommendations.

Yet, national and international health authorities worldwide recommend that the influenza vaccine be given to protect people who are most likely to have serious health problems if they get H1N1 influenza. These include:

- Adults and children over six months of age who have certain underlying chronic conditions, such as respiratory diseases
- Pregnant women
- Further groups recommended by the WHO experts include
 - healthy young adults,
 - healthy children,
 - healthy older adults
 - the elderly

Vaccination is also strongly recommended for people who may transmit influenza to those at high risk. Decreasing the transmission of influenza from caregivers and household contacts will reduce influenza-related deaths among those at high risk.

3. Should healthcare workers be vaccinated??

Yes, they should be vaccinated against H1N1 influenza, just like they should be vaccinated against seasonal influenza annually. Although healthy adults do not belong to the at-risk population, there are indeed good reasons for healthcare providers to get immunised against influenza, especially when they have regular contacts with patients and high-risk patients.

First of all, healthcare workers should not pose a risk to their own patients: healthy adults who take care of patients at risk of developing complications when they get influenza should also get their H1N1 vaccine.

Secondly, healthcare workers should be able to provide care for their patients when they need it, particularly during an influenza pandemic. Seeing that immunisation of healthy adults substantially reduces absenteeism from work, immunisation provides healthcare workers the opportunity to keep taking care of their patients when they are needed the most.

Thirdly, it is important to protect those who protect others against health hazards. Just as adult airline passengers are instructed when the cabin pressure falls to put on their automatic drop-down oxygen mask first – before fitting any to children – the same logic applies to healthcare workers dealing with influenza.

Yet, the rate of vaccination among healthcare workers is low across the globe. Although many countries recognize the need for their healthcare workers to be vaccinated, the fact remains that application of this principle in general remains low. Even in Europe – with some of the world's most pervasive healthcare systems – vaccination rates among healthcare workers is generally less than 25 percent.

4. Why are different countries targeting different groups for immunization?

Conditions such as the spread or severity of H1N1 influenza as well as local capacity to mount vaccination programmes differ from country to country and even from region to region. As a consequence, the groups targeted by local authorities may also differ. Both WHO and European Union experts stress the importance of adapting vaccination recommendations to meet local conditions.

5. What is the role of the EU in the fight against the H1N1 pandemic?

The EU, particularly through its European Centre for Disease Prevention and Control (ECDC), carries out a range of activities to provide a solid scientific base for influenza control in Europe and to improve preparedness for a pandemic at the local level, at the level of the regions within Europe, the European Union and the EU member states. It carries out evaluations on the degree of pandemic preparedness in the EU member states. In addition, through its European Medicines Agency, the EU can continue to work with manufacturers to help ensure that vaccines can be made available as quickly as possible and appropriate safety monitoring mechanisms are in place.

6. How safe are H1N1 vaccines?³

A wide range of measures is in place to monitor and review the safety of H1N1 pandemic vaccines, including regulatory assessment, clinical testing and wide-scale monitoring. This builds on the extensive safety record established with seasonal influenza vaccines over the last 60 years in a wide range of age groups.

H1N1 vaccines are currently undergoing clinical testing in thousands of subjects, and regulators will review these new clinical data as they become available. In many cases H1N1 vaccines are based on previously approved prototypes or approved seasonal influenza vaccines for which significant clinical data are already in place. New vaccines not based on previously approved products require additional clinical studies.

7. Can pandemic vaccines be approved for use very quickly without new clinical data?

Regulatory authorities have developed processes to accelerate the approval of vaccines and to allow rapid use without compromising safety. These procedures build on the extensive experience gained with seasonal influenza vaccines. This experience shows that changing the viral strain in vaccines produced using the same manufacturing, quality and control processes does not substantially affect the safety or protection offered. This allows regulators to review vaccines based on previously approved seasonal or prototype pandemic vaccines on the basis of strain change data for the new H1N1 virus. In addition, H1N1 vaccines are undergoing clinical studies in thousands of subjects and the results will also be reviewed by regulators when available. New H1N1 vaccines that are not based on previously approved products will require additional clinical studies.

8. How many different vaccines will be produced and how do they differ?

WHO has confirmed that currently there are approximately 30 candidate vaccines. Most contain killed viruses produced in eggs, while some are manufactured in cell culture and some are live attenuated vaccines. Some vaccines contain adjuvants while others do not. Irrespective of any differences, the vaccines must go through rigorous review and approval by regulatory authorities before wide-scale use is permitted.

9. What is an adjuvant?²

Adjuvants are substances that can be added to human vaccines. They 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: they improve the immune response whilst the dose size can be decreased. The latter is an excellent way to increase global vaccine manufacturing capacity. Compared to the normal antigen dose of 15 µg in seasonal influenza vaccines, an adjuvanted vaccine would only need to contain as little as 4 µg of antigen or less, in a two dose regimen, to be effective. To date, several adjuvants have met regulatory standards for safety. These include aluminium salts (which have been used safely in seasonal vaccines in the past) and complex oil in water emulsions. Active research and development programmes are ongoing to develop more new generations of adjuvants that are safe and antigen-sparing and broaden the immune response against influenza when incorporated in seasonal and pandemic vaccines.

10. Are the adjuvants contained in a number of new H1N1 vaccines safe?

WHO experts support the production and use of adjuvants in H1N1 vaccines, particularly in light of their potential to stretch vaccine supplies and protect against different, related viral strains. In addition, there is significant clinical evidence supporting the use of adjuvants in influenza vaccines.

The adjuvants used in H1N1 vaccines have undergone clinical trials in tens of thousands of subjects, and further testing is now underway in thousands more. The experience gained with vaccines containing these adjuvants, both in clinical studies and wider immunization campaigns, shows that their overall safety profile is similar to non-adjuvanted vaccines. Before any H1N1 vaccines can be used in broader immunization campaigns they must receive regulatory approval. This review process will be supported by extensive monitoring designed to rapidly detect any potential unexpected safety signal if it were to arise during more wide-scale use.

References

- ¹ for further information please see <http://www.who.int/wer/2009/wer8430.pdf> and <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/09/1252&format=HTML&aged=0&language=EN&guiLanguage=en>
- ² [101 Questions and Answers on Influenza](#), A.D.M.E. Osterhaus, D. De Pooter
- ³ WHO has issued a briefing paper outlining the safety of pandemic vaccines: http://www.who.int/csr/disease/swine-flu/notes/h1n1_safety_vaccines_20090805/en/index.html