

The WHO, what, why, where, and when of H1N1 vaccine

Dr Marie-Paule Kieny is director of the Initiative for Vaccine Research at the World Health Organization (WHO). The vast majority of cases of pandemic influenza A (H1N1) have been mild so far with few deaths. It remains to be seen whether the virus will mutate into a more virulent strain. Marie-Paule Kieny explains how WHO is supporting countries' efforts to protect their populations with vaccines that should become available as of this month.

Q: When will the first doses of vaccine for the pandemic influenza A (H1N1) be ready?

A: Some manufacturers announced in July that vaccine is available, but that doesn't mean it's ready for use, as it needs regulatory approval. Regulatory authorities are considering the best way to register these vaccines as quickly as possible. The consensus is that the first doses will be available to governments for use in September.

Q: Who will get vaccinated first? Who decides this?

A: Vaccine will not be available on the private market and governments will decide who gets vaccinated first. WHO recommends that health workers be the first, to protect the health system and allow them to care for influenza and other patients. The strategy a country takes will depend on its policy objectives and the availability of vaccine. WHO is working hard with manufacturers, governments and donors to ensure that developing countries can access vaccine as soon as possible to immunise their health workers, and when more vaccine becomes available, other groups will be immunised.

Q: How many different vaccine candidates will be available for A (H1N1)?

A: About 30. Most will be inactivated virus vaccines made in eggs, some will be killed virus vaccines made in cell cultures and a few will be live attenuated virus vaccines.

Q: Isn't it too early to produce vaccines because the pandemic virus could mutate?

A: Although the virus can mutate, we hope that there will be enough cross-protection through recognition of the new virus. But if the virus changes too much, we will need new vaccines.

Q: These must be the fastest vaccines ever produced. Given their fast-tracking, what is the guarantee of safety and efficacy?

A: The testing of influenza vaccines is different from that of other vaccines, because the rabies and measles vaccines for example do not change. Since influenza viruses evolve constantly, it is impossible to carry out a complete clinical analysis of seasonal influenza vaccines yearly because the composition changes each year to adapt to the virus and so you are always a year behind. A complete clinical evaluation is not needed also because manufacturers produce seasonal influenza vaccines using the same procedure and equipment, but for a different virus each year. All manufacturers will perform clinical trials to find out whether one or two

doses are necessary, to test it in special populations and to administer it jointly with other vaccines. Based on the extensive knowledge available on seasonal vaccines and the results obtained through evaluation of H5N1 avian influenza vaccines, there is no doubt that it will be possible to make effective H1N1 pandemic vaccines.

Q: What's been done to ensure that developing countries get enough vaccine?

A: It depends on what we mean by 'enough'. Some countries want to vaccinate every member of the population, but there is no way we can do this for the whole world. WHO has a cross-organisational operation that is in place to secure vaccines for developing countries. This is spearheaded by the Director-General's Office and the legal and vaccine departments. We are engaged in three types of activities. The first is to negotiate donations with manufacturers. Two have been announced: 100 million doses by Sanofi-Aventis and 50 million doses from GlaxoSmithKline. Second, we are working with other manufacturers to reserve a portion of their vaccine production for WHO at a reduced price. Third, we are working with governments to raise funds to purchase vaccines. We are also working with 11 vaccine manufacturers based in developing countries, providing them with seed financing and technical expertise to help them produce influenza vaccine domestically. We have also helped them access technology and given them sub-licences to use technology for producing live attenuated vaccine. These 11 companies will be manufacturing some of the 30 different expected vaccines.

Q: What happens if developing countries have only partial coverage?

A: Coverage will be partial and not only in developing countries. But we should not be 'hypnotised' by vaccines. There are other measures, such as social distancing, school closure, avoidance of large gatherings, antibiotics and personal hygiene. This is not like rabies, which is 100% fatal: we are talking about a disease from which most people recover very well. We will try to help countries to gain access to as much vaccine as possible, at least to preserve their health systems functioning, but there is just not enough vaccine for every country in the world to vaccinate every member of the population twice.

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