PRESS INFORMATION

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"Pre-pandemic" vaccines might offer protection but uncertainties remain

Two scientific reports published today by the European Centre for Disease Prevention and Control (ECDC) conclude that so called "pre-pandemic" vaccines might offer some protection against a future influenza pandemic. However, ECDC today stressed that there is no guarantee that the next human influenza pandemic will evolve from the current H5N1 avian influenza virus, on which the "pre-pandemic" vaccines currently under development are based. Different views were expressed by experts as to whether pre-pandemic vaccine would best be used in phase 5 or phase 6 of a pandemic. There was consensus, however, that it would be inadvisable to embark on a widespread vaccination programme in EU countries at present.

Zsuzsanna Jakab, Director of ECDC said:

"If there is an H5N1-based pandemic, the strategy of having stockpiled "pre-pandemic" H5N1 vaccines, even if the vaccines incompletely match the pandemic virus, may prevent more infections and deaths than waiting for specific "true" pandemic vaccines. That is a big if, though – there is no guarantee that H5N1 will evolve into a pandemic virus."

"The consensus in our expert groups was that widespread vaccination of people in EU countries would not, at present, be advisable: the vaccine should be deployed in phase 5 or phase 6 of a pandemic. That said, targeted vaccination of, for example, veterinarians and poultry workers could be a valid protection measure in the event of an H5N1 outbreak amongst birds in the EU."

Background

Following the development by a number of pharmaceuticals companies of "pre-pandemic" H5N1 vaccines, ECDC convened two Expert Advisory Groups (EAGs) to identify evidence and report back to ECDC and Member States that are considering using such vaccines. The rationale is that, unlike "true" pandemic vaccines, these "pre-pandemic" H5N1 vaccines can be made ahead of the emergence of pandemic virus.

The EAGs considered highly scientific questions over whether and how well "pre-pandemic" H5N1 vaccines will work against any H5-based pandemic, as well as public

health and operational questions concerning when such vaccines might be used, including the specific triggers, and for which groups in the population.

Although the EAGs fully expect and acknowledge that the science will change rapidly, they have provided answers to questions representing the best view based on the evidence available at the time of writing. They identified the need for further research, in particular with regard to the development of live influenza virus vaccines which offer great potential for producing vaccines more quickly in larger volumes.

Key findings of the Expert Group on Scientific Issues

- There are encouraging signs that some cross-protection is likely between the strain used in "pre-pandemic" H5N1 vaccines and a pandemic H5N1 strain.
- The efficacy and effectiveness of "pre-pandemic" H5N1 vaccines are unknown, but data from animal and bio-mathematical models indicates likely effectiveness even with a vaccine of modest efficacy, provided that it is administered in good time and coverage is adequate.
- One dose of "pre-pandemic" H5N1 vaccine may have some positive effects but two doses are recommended for protection.
- The shelf life of a "pre-pandemic" H5N1 vaccines is at least one year, based on the data from seasonal influenza vaccines.
- The risk of immunologic "mal-reaction" between the "pre-pandemic" H5N1 vaccine strain used and the pandemic strain is considered to be low.

Key findings of the Expert Group on Public Health & Operational Issues

- The group that would most benefit from vaccination with a "pre-pandemic" H5N1 vaccine will change with the evolving profile of the developing pandemic and also depend on the timing of the use of the vaccines. However, there are particular benefits in early vaccination of poultry workers, veterinarians, healthcare workers and laboratory staff, social care and other "front" line staff, and other vulnerable groups.
- The trigger points for vaccination will vary for each group according to resources and organisation of care, but should be defined as far in advance as possible.
- There may be some reduced infections in offering "pre-pandemic" H5N1 vaccines with reduced quantities of antigens to a great number of people than a higher amount of antigen to fewer people.

- Substantial continuous investment is needed in order to reduce the impact of a pandemic through “pre-pandemic” H5N1 vaccines, but – if an H5N1 pandemic does occur - this may be cost-effective.

- A system for gathering and sharing epidemiological information needed should be planned in advance and tested during a normal seasonal influenza epidemic. ECDC in conjunction with the MS, WHO EURO and EMEA has been planning these activities as part of the “Surveillance in a Pandemic” project.

- Pre-planned trials in key groups and routine seasonal influenza vaccine systems should be able to address rapid assessment of effectiveness when the “pre-pandemic” H5N1 vaccine is deployed.

Further information:
http://ecdc.europa.eu/Health_topics/Pandemic_Influenza/Guidance.html

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