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Safety of pandemic vaccines

Pandemic (H1N1) 2009 briefing note 6

6 AUGUST 2009 | GENEVA -- WHO is aware of some media reports that have expressed concern about the safety of vaccines for pandemic influenza. The public needs to be reassured that regulatory procedures in place for the licensing of pandemic vaccines, including procedures for expediting regulatory approval, are rigorous and do not compromise safety or quality controls.

Vaccines are among the most important medical interventions for reducing illness and deaths during a pandemic. However, to have the greatest impact, pandemic vaccines need to be available quickly and in large quantities.

During the 1957 and 1968 pandemics, vaccines arrived too late to be used as an effective mitigation tool during the more severe phases of the pandemics. Influenza vaccines had not yet been developed when the 1918 pandemic swept around the world, eventually killing an estimated 50 million people.

In 2007, as part of preparedness for an influenza pandemic, WHO worked together with health officials, regulatory authorities, and vaccine manufacturers to explore a broad range of issues surrounding the regulatory approval of pandemic vaccines. [1]

Ways were sought to shorten the time between the emergence of a pandemic virus and the availability of safe and effective vaccines. Different regulatory pathways were assessed, and precautions needed to ensure quality, safety, and effectiveness were set out in detail.

Fast-track procedures for approval

Regulatory authorities have shown great flexibility in developing procedures for fast-tracking the approval and licensing of pandemic vaccines.

In some cases, pandemic vaccines are not regarded by regulatory authorities as entirely "new" vaccines, as they build on the technology used to produce vaccines for seasonal influenza, established procedures for testing and regulatory control, and an extensive body of safety data.

In such cases, approval procedures are similar to those applied to "strain changes" made each year when seasonal vaccines are modified to match circulating viruses in the Northern and Southern Hemispheres.

Specific regulatory procedures have been devised to expedite the approval of pandemic vaccines. In the USA, for example, fewer data are required when the manufacturer already has a licensed influenza vaccine and intends to use the same manufacturing process for its pandemic vaccine.

In the European Union, the European Medicines Agency uses a rolling review procedure whereby manufacturers can submit sets of data for regulatory review as they become available, without having to wait until all data can be submitted together in a single formal application.

Also in Europe, some manufacturers have conducted advance studies using a so-called "mock-up" vaccine. Mock-up vaccines contain an active ingredient for an influenza virus that has not circulated recently in human populations and thus mimics the novelty of a pandemic virus. Such advance studies can greatly expedite regulatory approval.

Special safety concerns

Influenza vaccines have been used for more than 60 years and have an established record of safety in all age groups. While some serious adverse events have been reported, these have been rare.

Nonetheless, special safety issues will inevitably arise during a pandemic when vaccine is administered on a massive scale. For example, adverse events too rare to show up even in a large clinical trial may become apparent when very large numbers of people receive a pandemic vaccine.

Some adverse events will be coincidental – that is, associated in time with vaccine administration, yet not directly caused by the vaccine. Genuine adverse events directly caused by the vaccine may also occur, but cannot be predicted in advance. Given the safety record of seasonal vaccines, such events are expected to be rare.

Time constraints mean that clinical data at the time when pandemic vaccines are first administered will inevitably be limited. Further testing of safety and effectiveness will need to take place after

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International sharing of data from such post-marketing surveillance will be vital in guiding risk-benefit assessments and determining whether changes in vaccination policies are needed. WHO has developed standardized protocols for data collection and reporting in real-time, and will communicate findings to the international community via its web site.

[1] [Regulatory preparedness for human pandemic influenza vaccines. Report of a WHO Expert Committee on Biological Standardization. Geneva: World Health Organization, 2007 \[pdf 625kb\]](#)

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