



Safety of pandemic vaccines

Pandemic (H1N1) 2009 briefing note 16

19 NOVEMBER 2009 | GENEVA -- To date, WHO has received vaccination information from 16 of around 40 countries conducting national H1N1 pandemic vaccine campaigns. Based on information in these 16 countries, WHO estimates that around 80 million doses of pandemic vaccine have been distributed and around 65 million people have been vaccinated. National immunization campaigns began in Australia and the People's Republic of China in late September.

Vaccination campaigns currently under way to protect populations from pandemic influenza are among the largest in the history of several countries, and numbers are growing daily. Given this scale of vaccine administration, at least some rare adverse reactions, not detectable during even large clinical trials, could occur, underscoring the need for rigorous monitoring of safety. Results to date are encouraging.

Common side effects

As anticipated, side effects commonly reported include swelling, redness, or pain at the injection site, which usually resolves spontaneously a short time after vaccination.

Fever, headache, fatigue, and muscle aches, occurring shortly after vaccine administration, have also been reported, though with less frequency. These symptoms also resolve spontaneously, usually within 48 hours. In addition, a variety of allergic reactions has been observed. The frequency of these reactions is well within the expected range.

Guillain-Barre syndrome

To date, fewer than ten suspected cases of Guillain-Barre syndrome have been reported in people who have received vaccine. These numbers are in line with normal background rates of this illness, as reported in a recent study. Nonetheless, all such cases are being investigated to determine whether these are randomly occurring events or if they might be associated with vaccination.

WHO has received no reports of fatal outcomes among suspected or confirmed cases of Guillain-Barre syndrome detected since vaccination campaigns began. All cases have recovered. WHO recommends continued active monitoring for Guillain-Barre syndrome.

Investigations of deaths

A small number of deaths have occurred in people who have been vaccinated. All such deaths, reported to WHO, have been promptly investigated. Although some investigations are ongoing, results of completed investigations reported to WHO have ruled out a direct link to pandemic vaccine as the cause of death.

In China, for example, where more than 11 million doses of pandemic vaccine have been administered, health authorities have informed WHO of 15 cases of severe side effects and two deaths that occurred following vaccination. Thorough investigation of these deaths, including a review of autopsy results, determined that underlying medical conditions were the cause of death, and not the vaccine.

Safety profile of different vaccines

Campaigns are using nonadjuvanted inactivated vaccines, adjuvanted inactivated vaccines, and live attenuated vaccines. No differences in the safety profile of severe adverse events among different vaccines have been detected to date.

Although intense monitoring of vaccine safety continues, all data compiled to date indicate that pandemic vaccines match the excellent safety profile of seasonal influenza vaccines, which have been used for more than 60 years.

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