



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.

平成21年11月21日

新型インフルエンザワクチンに関する安全性評価のポイント（案）

新型インフルエンザワクチンの接種が10月19日より開始され、実施医療機関等から厚生労働省に副反応について報告されている。11月19日までに877例が報告され、うち、死亡が13例、死亡以外の重篤な症例が55例であった。

現時点で得られた情報に基づき、新型インフルエンザワクチン自体の安全性、接種事業の継続及びワクチン接種にあたって注意すべき点等の安全対策についての検討を行う必要がある。

1. ワクチンの基本的な安全性

- 医療従事者2万例コホートの健康状況調査によるワクチンの安全性
- 10月末までに医療従事者を中心に行われた接種の際に報告された副反応からみた安全性
- 新型インフルエンザワクチンの副反応報告の内容及び頻度についての季節性インフルエンザワクチンとの比較
- 現時点における新型インフルエンザワクチンの基本的な安全性の評価

2. 報告された死亡の評価について

- 11月以降に報告された死亡例が、心臓、腎臓、呼吸器等の機能に障害（重度の基礎疾患）を有する高齢者であることと優先接種対象者の接種開始との関連
- 基礎疾患自体により死亡した患者が、報告されている可能性
- 重度の基礎疾患を有する高齢者の個々の死亡事例とワクチン接種との関連
- 重度の基礎疾患を有する高齢者において、ワクチンの副反応が重篤な転帰に繋がる可能性。接種時及び接種後の注意点
- 重度の基礎疾患を有する高齢者に対する新型インフルエンザワクチンの安全性

3. 今後の対応について

- 重度の基礎疾患を有する高齢者における接種後の死亡報告の取扱い
- 重度の基礎疾患を有する者等への接種の取扱い、注意喚起の必要性