

ECDC HEALTH EDUCATION

On the use of specific pandemic influenza vaccines

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Introduction

This document summarises information on the use of specific pandemic influenza vaccines during the pandemic (H1N1) 2009. Its aim is to provide background information and guidance on pandemic vaccine use, along with options for prioritisation strategies based on the current scenario of the pandemic. The document draws on a previous ECDC risk assessment and a longer document on the use of specific pandemic influenza vaccines. Please refer to the note at the end of this document for further information on ECDC's previous publications.

Why is vaccination important?

In any pandemic, vaccination with a specific pandemic vaccine is considered one of the most effective countermeasures for protecting individuals.

The ECDC risk assessment for the pandemic is consistent with WHO's assessment of the influenza pandemic as moderate. The number of symptomatic cases is expected to be higher than for seasonal influenza, due to lower levels of pre-existing immunity in the population.

What issues need to be considered for the use of vaccines?

A number of issues require consideration when discussing pandemic vaccines and particular areas of uncertainty remain, including the following:

- pandemic vaccines will not become available all at once;
- efficient planning for distribution will be required;
- ensuring vaccine supply will be difficult in a reasonable timeframe; and
- strategic use of vaccines, after careful prioritisation between different population groups, will be important to maximise the benefit of the available vaccines.

What are the objectives of vaccination?

The objectives of a pandemic vaccination strategy for priority groups can be considered in two broad categories which are not mutually exclusive:

- a) to protect the individuals that may be at greatest risk for severe disease; and
- b) to protect individuals essential to the pandemic response and other essential services.

The overall objectives of vaccination should be specified before deciding who should get the vaccination and how to prioritise between populations.

Objectives may legitimately differ by country and/or region due to resources, the way health systems are organised, the availability of vaccines and related distribution issues.

Who should get the vaccine?

When considering who should get vaccinated first, three categories need to be considered:

- risk groups: those at higher risk of severe disease;
- healthcare workers: in this context, this group especially includes those with direct, first-line patient contact; and
- essential service groups: people performing functions that are critical for the functioning of society.

The influenza A(H1N1)v virus is a novel virus. As each pandemic has distinct features and is different from seasonal influenza, pandemic risk groups may also differ somewhat from those for seasonal influenza strains. In this sense, and because of the large numbers of people who may get sick at once, different strategies may come into play, with greater emphasis on the need to maintain healthcare and other essential services by immunisation.

According to current (August 2009) evidence on the pandemic (H1N1) 2009, the following can be identified as risk groups:

- people aged less than 65 years with chronic underlying conditions, namely:
 - chronic respiratory diseases;
 - chronic cardiovascular diseases;
 - chronic metabolic disorders (notably diabetes);
 - chronic renal and hepatic diseases;
 - persons with deficient immunity (congenital or acquired);
 - chronic neurological or neuromuscular conditions; and
 - any other condition that impairs a person's immunity or prejudices their respiratory function.
- young children (especially those younger than two years old); and
- pregnant women.

This list differs somewhat from the groups for whom many countries recommend seasonal influenza immunisation, especially with regard to people 65 years and older.

Generally, older people seem to be at lower risk of infection — possibly due to prior immunity — but there are indications that if they become infected, they suffer more severe disease than younger adults.

In addition, there are other groups to whom immunisation may be offered based on specific arguments, even though they are not at higher risk of severe disease. They include:

- all healthcare workers: there are advantages in offering immunisation to people who care for others among whom immunisation may not be effective (e.g. people under treatment with immune suppressive therapy or others for whom vaccines are more likely to have lower effectiveness);
- people in close contact with babies: babies younger than six months of age cannot, at this stage, be immunised because of the lack of data on immunogenicity and safety. Therefore, there are arguments for offering vaccination to those that are in closest contact with them;

- essential workers responsible for the response to the pandemic and for delivering other essential functions; and
- children and young people, since initial epidemiological information shows they are experiencing high attack rates (albeit of mild disease) and may be particularly important in amplifying local outbreaks.

The final section of the population to be immunised — the target group — depends on each country's pandemic plan and varies from country to country. In some countries, the target group is (almost) the entire population while in others, it represents only specific segments of the population.

Monitoring and evaluation

Monitoring and evaluation are essential for any vaccination programme. In the case of the new specific pandemic vaccines it becomes an especially high priority to monitor the effectiveness and safety of the newly developed vaccines. Due to the possible continuous mutation of the virus, effectiveness of the pandemic vaccines has to be measured in the field in the post-marketing phase. Although influenza vaccines are among the safest, immunisation vaccine safety has to be carefully monitored during the post-marketing phase, in order to ensure the early detection and prompt assessment of any credible adverse event that seems to be associated with the vaccine. This will be especially important with a lower severity pandemic and one affecting groups where reported adverse reactions may be particularly difficult to assess because of higher incidence of background illness (young children, pregnant women, and those with other conditions).

Note: This document is a summary of the Interim Guidance produced by ECDC on use of specific pandemic influenza vaccines during the pandemic (H1N1) 2009.

The full document is available at <http://www.ecdc.europa.eu>, search term: 'pandemic vaccine interim guidance'. Its aim is to provide background information, guidance on pandemic vaccine use and options for prioritisation strategies, with a special focus on the current pandemic (H1N1) 2009.

The ECDC interim guidance is based on the current scenario of the pandemic (H1N1) 2009. As more data, evidence and opinions become available, this ECDC document will be updated along with the ongoing ECDC risk assessment of the situation.