Influenza

Program Management

SAGE encouraged all countries to consider their preparedness for a potential influenza pandemic, recognizing that it would occur before strain-specific vaccine can be made in significant quantities.

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006

WHO encourages initiatives to raise awareness of influenza and influenza vaccination among healthcare workers and the public, including definition of national targets for immunization programmes.

WHO strongly emphasizes the importance of raising the public consciousness of influenza and its complications as well as of the beneficial effects of influenza vaccination. (page 287)

Influenza vaccines (WHO position paper)

Procurement

WHO’s global action plan identifies 3 main approaches that may be used to increase the capacity for producing pandemic influenza vaccines. These are: increase seasonal vaccine uptake to stimulate market forces and increase production capacity, increase or establish production capacity for pandemic vaccines in industrialized and developing countries independent of the demand for seasonal influenza vaccine, and implement research and development of vaccines based on new technologies.

WHO has developed procedures to facilitate the rapid transfer of strains and the release of sequence information and details of the procedures could be found on WHO’s web site (http://www.who.int/csr/disease/avian_influenza/guidelines/h5n1sequences2006_08_23/en/index.html).

Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006
**Influenza**

**Vaccine Handling**

Live attenuated influenza vaccines have been used for several decades in Russia and have recently been developed in the USA, for intranasal application.

It must be stored frozen (-15°C to -25°C), and thawed for up to 60 hours at +2°C to +8°C before use, but it should not be refrozen. Because temperature cycling could affect product stability, it should be stored in a frost-free freezer. A refrigerator stable formulation (to be kept at +2°C to +8°C) is in development.

**Schedule**

A trivalent live cold-adapted vaccine (Flumist) has been developed for intra-nasal spray delivery . . .

The vaccine has been licensed in the USA for vaccination of persons from 5-49 years of age, in view of side effects in younger children (wheezing, nasal congestion) and absence of data in the elderly. The vaccine is safe, effective, and shows remarkable genetic stability, but it has to be kept at -18°C.
Based on data from industrialized countries, and listed in order of priority, the following groups of individuals may be targeted for vaccination (against influenza) in order to reduce the incidence of severe illness and premature death.

1. Residents of long-term care facilities for elderly people and the disabled.
2. Elderly non-institutionalized individuals with chronic conditions such as pulmonary and cardiovascular illness, metabolic diseases including diabetes mellitus and renal dysfunction, and various types of immunosuppression, including people with acquired immunodeficiency syndrome (AIDS) and transplant recipients.
3. All adults and children aged >6 months with any of the conditions mentioned above.
4. Elderly individuals who are above a nationally defined age limit, irrespective of other risk factors. Although the appropriate age for general vaccination may be considerably lower in countries with poor living conditions, most countries define the age limit to be >65 years.
5. Other groups defined on the basis of national data and capacities, such as contacts of high-risk people, pregnant women, health-care workers and others with key functions in society, as well as children 6-23 months of age.

Influenza vaccines (WHO position paper)

In terms of protective efficacy, the live influenza vaccines appear to be comparable with the TIVs (trivalent, inactivated influenza vaccines.) However, CAIV-T (cold-adapted influenza vaccine) is licensed only for healthy people aged 5-49 years, given reports of an increase in reactive airway disease in vaccinees <5 years of age and insufficiently documented protective efficacy in older people.

Influenza vaccines (WHO position paper)

**Vaccine Administration**

TIVs (trivalent, inactivated influenza vaccines) are injected into the deltoid muscle (vaccinees aged >1 year) or the antero-lateral aspect of the thigh (vaccines aged between 6 and 12 months). Inactivated influenza vaccines will not interfere with concomitantly administered diphtheria/tetanus/pertussis (DTP) or other childhood vaccines.

Influenza vaccines (WHO position paper)
## Influenza

### Contraindications

Except for anaphylactic allergic reactions to egg or other components of the (trivalent, inactivated influenza) vaccines, there are no contraindications to the use of these vaccines in age groups >6 months.

*Influenza vaccines (WHO position paper)*

Following nasal administration, (t)ransmission of the (influenza) vaccine virus to exposed non-immune people appears to be very rare. However, as a precaution the vaccine should not be given to highly immunosuppressed individuals or their close contacts.

Contraindications for use (of CAIV-T influenza vaccine) include anaphylactic reactions to eggs, a history of Guillain-Barré syndrome, patients aged <18 years on long-term aspirin therapy, pregnancy during the first trimester, and various states of immunosuppression.

*Influenza vaccines (WHO position paper)*

(Inactivated) influenza vaccination in pregnancy is considered safe and is recommended for all pregnant women during the influenza season. This recommendation is motivated not only by the potential severe course of influenza during pregnancy, but also in order to protect infants against influenza during their vulnerable first months of life.

*Influenza vaccines (WHO position paper)*
**Adverse Event**

During some influenza seasons, TIVs (trivalent, inactivated influenza vaccines) have been associated with a slight increase in the risk of Guillain-Barré syndrome in older adults (about 1 case added to the background incidence of about 20 cases per million vaccine recipients). A virosomal intranasal formulation of TIV was withdrawn from the market because of an association with an increased incidence of facial palsy. A sporadic, self-limiting oculo-respiratory syndrome has been reported following TIV immunization, especially in relation with the use of a particular vaccine product in Canada. This excess risk was corrected through a modification of the manufacturing process. Except for anaphylactic allergic reactions to egg or other components of the vaccines, there are no contraindications to the use of these vaccines in age groups >6 months.

*Influenza vaccines (WHO position paper)*

**Immunization Coverage**

In 2003, the World Health Assembly urged Member States with influenza vaccination policies to increase vaccination coverage of all people at high risk and to aim at vaccination coverage of elderly people of at least 50% by 2006 and 75% by 2010.

*Influenza vaccines (WHO position paper)*
Influenza

Surveillance of Vaccine Preventable Disease

Improved coverage of WHO’s Global Influenza Surveillance Network should be achieved to obtain better information on the epidemiology of influenza A and B.

Surveillance of influenza is of particular importance in rural areas where potential animal hosts and humans live in close proximity, since it is in such areas that new viral recombinants are likely to originate.

Influenza vaccines (WHO position paper)

WHO strongly encourages the implementation of epidemiological surveillance, disease burden assessments and, where appropriate infrastructure is available, demonstration projects to estimate the impact of vaccination on disease in poor countries.

Further exploration of the safety and cost-effectiveness of introducing influenza vaccination into national immunization programmes is clearly warranted.

Influenza vaccines (WHO position paper)

Research

WHO’s global action plan identifies 3 main approaches that may be used to increase the capacity for producing pandemic influenza vaccines. These are: increase seasonal vaccine uptake to stimulate market forces and increase production capacity, increase or establish production capacity for pandemic vaccines in industrialized and developing countries independent of the demand for seasonal influenza vaccine, and implement research and development of vaccines based on new technologies.

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Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

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Influenza

SAGE recommends that while influenza vaccine research has considerable momentum, investigation into the development of vaccines against subtypes with pandemic potential other than H5N1 should continue (for example, H7).

So far, mainly healthy adults have been enrolled in clinical trials with H5N1 candidate vaccines. SAGE stresses the importance of evaluating their safety and immunogenicity in children and immunosuppressed individuals.

Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

(Regarding pandemic influenza vaccine, more) research is therefore needed in 4 major areas: correlates for protection, novel adjuvants, whole virion vaccines, and immunogenicity and growth of vaccine strains.

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006

(S Regarding influenza vaccine development,) SAGE encouraged manufacturers and national regulatory authorities to strengthen mechanisms to rapidly share the results of clinical trials with the global community.

SAGE stressed the importance of investigating the use of pandemic vaccines to prime populations against H5N1 viruses and to anticipate the regulatory and other criteria relevant to their use;

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006

WHO strongly encourages the implementation of epidemiological surveillance, disease burden assessments and, where appropriate infrastructure is available, demonstration projects to estimate the impact of vaccination on disease in poor countries.

Further exploration of the safety and cost-effectiveness of introducing influenza vaccination into national immunization programmes is clearly warranted

Influenza vaccines (WHO position paper)
Furthermore, studies are strongly encouraged to characterize risk factors and the impact of influenza in resource-limited countries. Studies to evaluate the effectiveness of vaccines in such populations are recommended.