#### Proposed Revisions to the 2005 WHO Position Paper on Influenza Vaccines, 2012

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# SAGE Influenza Working Group

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# SAGE Influenza Working Group

#### Terms of Reference

- Prepare for a SAGE evidence-based review and updating of WHO recommendations on use of seasonal influenza vaccines, with a particular focus on low and middle income countries and with a view to update the 2005 WHO influenza vaccine position paper.
- Prepare for a SAGE discussion on coverage goals for seasonal influenza vaccination to be proposed to the WHA
- Identify gaps in evidence
- Provide advice about pandemic influenza vaccine preparedness

# 2005 WHO Position Paper on Influenza Vaccines

#### WHO position

Main purpose of seasonal influenza vaccination is to avoid severe influenza and complications.

Acknowledges the following:

- Around 50 countries (mainly industrialized) offer influenza vaccination to nationally defined high-risk groups, including the elderly and individuals with cardiovascular, metabolic, renal or immune-suppressing conditions.
- Differences in health priorities & limitations of health budgets have restricted common use of influenza vaccine to high-risk groups in industrialized countries.
- Groups at particular risk of severe influenza in developing countries are less well characterized. Data mostly from industrialized countries.

### 2005 WHO Position Paper on Influenza Vaccine

- In order of priority, the following groups may be targeted for vaccination to reduce the incidence of severe illness and premature death
  - 1. Residents of long-term care facilities for the elderly & the disabled
  - 2. Non-institutionalized elderly with chronic heart or lung diseases, metabolic or renal disease, or various types of immunodeficiencies
  - 3. All individuals >6 months of age with any of the conditions listed above
  - 4. Elderly above a nationally defined age limit, irrespective of other risk factors
  - 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

# 2005 WHO Position Paper on Influenza Vaccines

- Influenza vaccination in pregnancy is considered safe and is recommended for all pregnant women during the influenza season
  - Potential severe course of influenza during pregnancy
  - Need to protect infants during their vulnerable first months of life
- Encourages initiatives to raise awareness of influenza and influenza vaccination among health care workers and the public, including definition of national targets for immunization programmes

# Conceptual Framework

| Issues                  | Pregnant<br>Women | Healthcare<br>workers | Children<br>(<2 years);<br>(2-5 years) | Elderly | Individuals<br>with<br>Underlying<br>Conditions |
|-------------------------|-------------------|-----------------------|--|---------|---|
| Burden of<br>Disease    |                   |                       |  |         |   |
| Vaccine<br>Performance  |                   |                       |  |         |   |
| Cost-<br>Effectiveness  |                   |                       |  |         |   |
| Operational<br>Concerns |                   |                       |  |         |   |

Working Group's Assessment of Influenza Risk and Influenza Vaccine Characteristics in Various Risk Groups

| Risk Group                         | Feasibility of Delivery | Disease<br>Severity | Vaccine<br>Effectiveness | Indirect<br>Benefits |
|------------------------------------|-------------------------|---------------------|--------------------------|----------------------|
| Pregnant<br>women                  | ++                      | +++                 | +++                      | ++                   |
| Healthcare<br>workers              | ++                      | +                   | +++                      | +                    |
| Children, 2-5<br>years             | +                       | ++                  | ++                       | -                    |
| Children, < 2<br>years             | ++                      | +++                 | +                        | -                    |
| Elderly                            | +                       | +++                 | +                        | -                    |
| Underlying<br>Health<br>Conditions | +                       | +++                 | +                        | -                    |

# Summary of the Working Group's Key Conclusions

- The Working Group concluded that influenza vaccines are effective and safe and warrant increased use in all countries
- The Working Group identified five subgroups of people as recommended target groups for annual influenza vaccination
- Countries with existing influenza vaccination programs that target any of these subgroups should continue such programs

# Summary of the Working Group's Key Conclusions (continued)

- Any country using influenza vaccine annually should include pregnant women among their target groups
- Countries should decide which other groups to target for influenza vaccination, based on burden of disease, cost-effectiveness, feasibility, and other appropriate considerations
- Increased use of seasonal influenza vaccine globally supports enhanced influenza vaccine production capacity and thereby contributes to influenza pandemic preparedness

# Proposed Recommendations

- In countries using or considering introducing seasonal influenza vaccination, the Working Group proposes that SAGE:
  - 1. Recommend influenza vaccination of all pregnant women as the highest priority group
  - 2. Recommend that, based on local circumstances (e.g. burden of disease, vaccine availability, cost-effectiveness considerations, competing priorities, and programmatic constraints), countries consider annual influenza vaccination of healthcare workers, children (< 2 years and 2-5 years of age), the elderly, and individuals with underlying health conditions, with countries to decide the relative priority to assign to targeting these groups for influenza vaccination.

# Proposed wording for WHO Position Paper on Influenza Vaccines

#### Pregnant Women

- Pregnant women should be vaccinated against influenza. In countries considering initiating or expanding vaccination programs for influenza, SAGE recommends pregnant women as the highest priority group for vaccination.
- This recommendation is based on compelling evidence of a substantial risk of severe disease in pregnant women, evidence that vaccine is effective against severe disease, and the evidence supporting secondary protection of infants under 6 months, in whom disease burden is also high, as well as operational feasibility.

# Proposed wording for WHO Position Paper on Influenza Vaccines

#### Other Groups, Healthcare Workers

- Healthcare workers are an important priority group for influenza vaccination. Vaccination of the healthcare worker not only protects the individual, but also maintains healthcare services during influenza epidemics and protects vulnerable patients.
- Development of influenza vaccination programs targeting health care workers is also an important pandemic preparedness strategy.

#### Proposed wording for WHO Position Paper on Influenza Vaccines

#### Other Groups, Children

- Children under 2 years are recognized as a priority group for vaccination because of a high burden of severe disease. Preventing influenza disease in this influenza-naïve population is currently challenging, as effective immunization requires two doses and is highly dependent on vaccine match. However, children under 2 years should be considered as an additional target group for influenza immunization when sufficient resources are available for influenza prevention and with due consideration for competing health priorities and operational feasibility. The future availability of vaccines more effective at priming will further increase the benefits and potentially reduce the need for two doses of influenza vaccine in this age group.
- Children aged 2-5 have a high burden of disease, although less than <2's, and may respond better to vaccination with Trivalent Inactivated Vaccine (TIV). Live Attenuated Influenza Vaccine (LAIV), when available, provides broader and higher levels of protection in this age group.

# Proposed wording for WHO Position Paper on Influenza Vaccines

#### Other Groups, Elderly

Elderly persons have the highest risk of mortality, and severe disease, and vaccination of this high risk group has traditionally been a main focus of vaccine policy. This continues to be an appropriate target group for vaccination. However, delivering annual immunization to this group requires considerable ongoing investment, and increasing evidence demonstrates that vaccines may be less effective in this population, compared to younger adults

#### Proposed wording for WHO Position Paper on Influenza Vaccines

#### Other Groups, Individuals with Underlying Health Conditions

Persons with specific chronic diseases (see table) are at high risk for severe influenza illness. These groups have often been targeted for influenza vaccination, and continue to be an appropriate target group for vaccination. However, identification of these individuals in many settings is often challenging and requires considerable ongoing investment.

# Criteria for countries to consider in prioritization of target groups for influenza vaccination

- Contribution of risk group to the overall influenza disease burden in population
- Disease severity within individual risk group
- Vaccine effectiveness in the risk group
- Feasibility of delivery
- Indirect effects
- Cost-effectiveness
- Opportunity cost

# Summary

- Influenza working group recommends substantial changes in WHO's position on influenza vaccine
- New recommendations support continued use of influenza vaccine among groups traditionally targeted, especially in high income countries (e.g. the elderly and those with underlying health conditions), but give highest priority to pregnant women, so as to protect them and their newborn infants
- Increased use of seasonal influenza vaccine leads to improved capacity to produce a pandemic influenza vaccine rapidly and thus is an important component of influenza pandemic preparedness.