Influenza Vaccine Update

The potential for an influenza pandemic with enormous mortality and morbidity poses an increasing threat to our world of easy international travel, concentrated population centers and large numbers of people not receiving adequate health care. Vaccines form a key intervention to prevent a pandemic due to the avian influenza virus or another new virus.

Seasonal influenza vaccine

- Seasonal influenza vaccine is primarily used in the developed world to protect elderly and those with immuno-suppressed conditions. Every year a new vaccine has to be developed depending on the virus that is likely to circulate that year.
- Resource poor countries of the developing world generally have no policy on use of seasonal influenza vaccine. However, there is a need to assess carefully the burden of the disease and evaluate cost-benefit analysis for possible policy change.
- The production capacity for current influenza vaccine globally is estimated to be 350 million doses of inactivated trivalent vaccine. A planned expansion for extra vaccine production capacity in the next 2-3 years can take this figure to 780 million doses, and with monovalent vaccine production instead of a trivalent vaccine, the capacity could go further up to 2300 million by 2009. Still far less than what is required to vaccine the global population of 6.3 billion.
- Current vaccine production capacity is concentrated mostly in nine industrialized countries: Australia, Canada, France, Germany, Italy, Japan, The Netherlands, The United Kingdom and The United States.

Approaches to increasing supplies of pandemic influenza vaccine

- Presently many manufacturers are engaged in developing pandemic influenza vaccines against H5N1 avian influenza virus, and some against other avian viruses (H9N2, H5N2, and H5N3) with clinical trials having been completed or are ongoing.
- Three main strategies for increasing vaccine supply have been identified by WHO as a part of it's Global pandemic influenza action plan to increase vaccine supply: 1) developing an immunization policy to increase demand for seasonal vaccines, 2) increasing influenza vaccine production capacity, and 3) promoting research and development for new influenza vaccines.
- Among possible strategies for increasing production capacity include improving production yield of H5N1-based vaccines, use of adjuvants with proven safety, and testing intradermal route of administration needing lower doses.
- According to SAGE (Strategic Advisory Group of Experts on Immunisation), there are preliminary data available that suggest that vaccines are safe, relatively immunogenic at lower doses and may offer on the basis of preliminary evidence from serological data cross-protection against other H5N1 strains.

Ensuring access to pandemic vaccines

- There is an uncertainty regarding which virus would be the cause of a pandemic. Even when an emergence of a pandemic virus is announced, it would take easily 3-6 months when first batch of the pandemic vaccine will be available for use. Unfortunately, even when the vaccine is developed, it is very unlikely that it would be available for use in developing countries.

- Two main strategies are being advocated by WHO to enhance access by countries who have no capacity to develop a vaccine: 1) in short-term, establishing a vaccine stockpile, and 2) on a longer-term, enhance production capacity including through partnership with developing countries.

Short-term strategy

As a short-term measure, an H5N1 stockpile could potentially prevent deaths as well as slow the spread of the disease in its early stages. Creation of a stockpile of vaccine against H5N1 will help countries without vaccine production capacity or the ability to purchase them from manufacturers. The stockpile could be used for attempting to contain limited early outbreaks of H2H transmission of H5N1 virus, or to immunize essential personnel in countries affected by an epidemic, thus preventing deaths and helping maintenance of functional health systems and other crucial national infrastructures.

- At the same time, operational guidelines that would govern the management and release of the stockpiled H5N1 vaccine and defining appropriate methods for monitoring use and evaluating outcomes.

Long-term strategy

- Long term measures would include an increase in production capacity, through improvements in vaccine-production technologies and formulations of vaccines, the construction of new plants, or the partial conversion of existing facilities used to produce vaccines for veterinary purposes. There is also a need for further research and development, including the development of novel vaccines that induce broad-spectrum and long-lasting immune responses. Capacity building, transfer of technology, and partnership between developed and developing countries and between International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and Developing Country Vaccine Manufacturers Network (DCVMN) are part of this long- term strategy.
- WHO has already awarded initial grants to approved vaccine manufacturers in 6 developing countries, 3 of which are in the SEAR, namely India, Indonesia and Thailand to increase the surge of capacity of pre-pandemic vaccine.