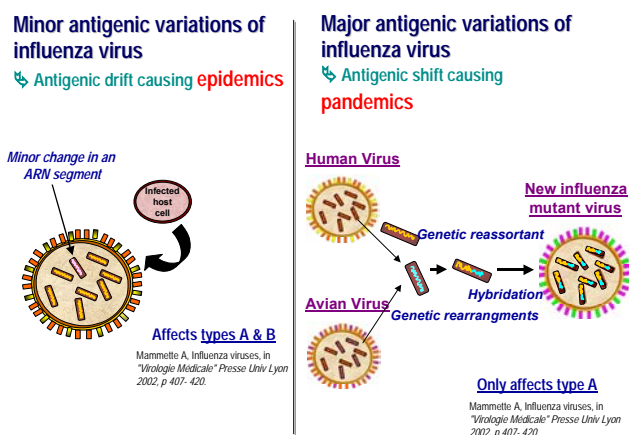




A Flu Pandemic: Are we prepared?

A flu pandemic will be triggered with the emergence of a novel influenza virus. Most authorities now agree that this will happen at some point in the future and the experience of previous influenza pandemics indicates the potential scale of the public health problem. In order to prepare for a future pandemic, measures to accelerate the development of pandemic vaccines and to increase current vaccine use are required.

What is the problem with flu virus?



Influenza viruses regularly undergo genetic mutations (antigenic drift), and this is why the composition of the flu vaccine used in the inter-pandemic period must be reformulated each year. New strains with different antigens appear periodically (antigenic shift) and consequently cause pandemics as there is no significant immunity in the population.

Should we worry about a pandemic?

The potential for a pandemic arises when three criteria are in place:

- a novel virus subtype must emerge to which the general population will have little immunity;
- the new virus must be able to replicate in humans and cause serious disease; and

- the new virus must be efficiently transmitted from person to person.

In January 2004 there was an explosive outbreak of influenza in poultry in a number of Asian countries. This disease was caused by a virus that was later identified as H5N1, a sub-type which had not previously infected man.

Subsequently, the first cases of human infection with influenza virus H5N1 were reported in Thailand and, unfortunately, most proved to be fatal.

Evidence strongly suggests that H5N1 is now endemic in parts of Asia, having established a permanent niche in poultry. Two of the criteria for a pandemic are thus in place and the opportunities for a pandemic virus to emerge are present.

Many authorities regard an influenza pandemic as the most significant global public health emergency caused by a naturally occurring pathogen. The impact is difficult to predict but the WHO estimates that a pandemic could kill up to 8 million people and have an economic impact running into billions of dollars. While the timing cannot be predicted, rapid international spread is certain once a virus with appropriate characteristics emerges.

"Nobody knows how bad it will be but there is no disagreement that this is just a matter of time. We can't be optimistic" Dr Lee – Director General, WHO

EVM's mission:

- to create a supportive environment for improved vaccine protection and coverage in the interest of the individual and the community;
- to promote vaccine R&D to meet new challenges for innovative vaccine applications against infectious and other types of diseases;
- to foster a favourable policy climate for the vaccine industry to bring new vaccines to the world.

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Planning for the future.

Contingency planning for an event in the future is often difficult to justify but there are two reasons to invest in pandemic preparedness:

- preparation will reduce the medical and economic effects of a pandemic; and
- preparing for the next influenza pandemic will provide benefits now.

What needs to be done

In the event of a pandemic, specific pandemic flu vaccines will need to be developed rapidly and then produced in extremely large quantities. Planning in advance is required to put in place two complementary actions:

- **accelerate the development of prototype pandemic vaccines; and**
- **anticipate the production demands required to produce pandemic vaccines**

Rapid development of Prototype Pandemic Vaccines

The “normal” procedure required for the testing and authorization of a vaccine requires about 6 months to complete. This lead-time could be considerably reduced by the early preparation of a “mock-up” or “prototype” vaccine that includes flu virus strains to which humans have no immunity (e.g. H5N1), the development and authorization of a “mock-up” registration file using the production process and final formulation of the future vaccine. With this work completed, a “variation” registration file could be submitted for fast track approval when a pandemic is declared.

The development of “prototype” vaccines”, however, represents a substantial investment (~ 11M€ per prototype) and vaccine manufacturers are discussing with the Commission and Member States ways that this could be equitably shared.

Determine needs for flu vaccines and adapt production

Vaccine capacity is directed to each flu season’s vaccine demand, with no reserve capacity. Currently, 90 million doses of influenza vaccines (trivalent vaccine) are used in Europe (2003-2004). In order to protect between 50 to 100% of the 450 million Europeans in case of a pandemic, an increase of vaccination coverage from 90 million doses up to 150 million doses (monovalent vaccine) is needed.

The lead-time to build and validate new manufacturing plant is about 4 years and this additional capacity therefore has to be in place before a pandemic, in order to provide the requisite number of doses.

At the moment, the WHO target for annual flu vaccine is to cover 75% of the recommended age and risk groups is not achieved in most European countries. The first element that should be met is the WHO target and then the established flu vaccination programmes could be progressively strengthened as indicated in the table. This would enable vaccine manufacturers to boost production to levels that would be able to cover the demands of a pandemic.

To meet pandemic vaccine needs current vaccination programmes should be strengthened by:

- Expansion of WHO recommendation of 75% coverage to +50 years age group and paediatric population.
- Increasing the coverage of at risk groups in < 50 years age group