S44-4 Vaccine development for novel influenza viruses and the remaining developmental issues

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Highly pathogenic H5N1 avian influenza viruses originating from Vietnam and Thailand have spread throughout Asian countries since the end of 2003. The number of human cases has exceeded 400 and the mortality rate is above 50%. Given this urgent situation, every vaccine manufacturer around the world has started the development of vaccines to counter this threat. Due to the low immunigenicity of H5N1 viruses, and based on past experiences, four major Japanese drug manufacturers have selected an alum adjuvanted whole virion vaccine for further development. The vaccine has been licensed because it was well tolerated and induced a good immune response in clinical studies.

The novel H1N1 virus originating from North America has rapidly spread throughout the world and the WHO reacted by raising its pandemic alert level to Phase 6 on June 11, 2009. Influenza vaccine manufacturers have responded to this decision by starting the development and production of vaccines. In Japan, it was decided to produce non-adjuvanted split vaccines based on experiences in 1976. The results of a clinical study showed that a single dose of a non-adjuvanted vaccine elicited a good immune response in healthy adults.

The following are some outstanding issues common to both H5N1 and H1N1 vaccines:

1. Securing the generation of high growth vaccine seeds
2. Securing the production of antigen assay reagents
3. Standardization of the method for measuring antibodies

The global issues listed above are still unresolved and continuing discussions between nations are still needed.