

Development of Cell-based Influenza H7N9 Vaccines for Pandemic Preparedness in Taiwan

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Avian-origin Influenza A(H7N9) viruses emerged as human pathogens in China in early 2013 and continue to cause human infections in winter seasons in 2014 and 2015 in China. Moreover, several imported cases have been detected in Hong Kong, Malaysia and Taiwan. Through financial support from Ministry of Health and Welfare, we initiated a task force in middle 2013 to develop cell-based influenza H7N9 vaccines for pandemic preparedness. Here are the milestones we have accomplished: 1) An egg-derived influenza H7N9 vaccine virus (NIBRG-268) was obtained from the WHO (World Health Organization) reference lab and adapted in MDCK cells; 2) Validation of a master virus bank was completed following international guidelines through an international contract research organization; 3) Influenza H7N9 whole virus vaccine antigen was manufactured using the microcarrier-based disposable bioreactor culture system and the liquid chromatography purification platform; 4) Hemagglutinin (HA) content of the purified vaccine antigen was quantified using single radial immunodiffusion and standard reagents obtained from the US FDA (Food and Drug Administration); 5) Immunogenicity and protection of the vaccine candidates adjuvanted with aluminum hydroxide were proved in ferret studies; 6) Preclinical safety of the vaccine candidates were proved in rat and rabbit studies; 7) We identified a local industry partner through non-exclusive technology transfer in April 2014 for conducting clinical trials; 8) Phase I and II clinical trials have been initiated in April 2015 by the industry partner. In conclusion, we have efficiently initiated a task force to respond to the urgent demand for influenza H7N9 pandemic preparedness. Continuous financial support is critical to increase efficiency of the task force from obtaining vaccine viruses to conducting clinical trials. The same model could be applied to other emerging novel influenza viruses.

Reference

Chia MY, Hu AY, Tseng YF, Weng TC, Lai CC, Lin JY, et al. Evaluation of MDCK Cell-Derived Influenza H7N9 Vaccine Candidates in Ferrets. *PLoS One*. 2015;10(3):e0120793.