

# IMMUNOGENICITY AND SAFETY OF AN INACTIVATED PANDEMIC H1N1 VACCINE PROVIDED BY THE THAI MINISTRY OF PUBLIC HEALTH AS A ROUTINE PUBLIC HEALTH SERVICE

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**Abstract.** A prospective study was conducted among 252 participants to study the immunogenicity of unadjuvanted inactivated H1N1 influenza vaccine, using a hemagglutination inhibition (HAI) assay, conducted on Days 0 and 21 following immunization. Adverse events (AEs) were monitored for by interview. The mean age of participants ( $\pm$ SD) was 45 ( $\pm$ 11) years. Seventy percent of participants had no history of major medical problems, 28% had a chronic illness and 2% were pregnant women. The HAI assay geometric mean titer (GMT) was 6.9 on Day 0 and 33.4 on Day 21 (4.8 times,  $p < 0.001$ ). The proportion of participants who had a HAI assay titers  $\geq 40$  was 7% (19/252) on Day 0. Those who had a titer  $\geq 40$  and/or a 4-fold rise in their HAI titer on Day 21 was 62% (155/252) ( $p < 0.001$ ). Fifty-six percent (142/252) had a four-fold increase in their HAI assay titer. Of the 19 subjects with a Day 0 HAI assay titer  $> 40$ , 10 (53%) had a four-fold increases in their HAI assay titer after vaccination. On multivariate analysis, only "older age" was associated with a lower probability of immune response (OR 0.5; 95%CI 0.3-0.8). No serious systemic AEs were reported. Mild erythema and local reaction on Day 2 were reported in 9% (23 of 252). The antibody response after a single dose of inactivated monovalent H1N1 vaccination in this study was relatively low, especially in the older age group. A booster H1N1 vaccine dose may be needed. The vaccine was safe and well tolerated.

**Keywords:** H1N1 vaccine, safety, immunogenicity, Thai

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