

VII – 1

## **Efficacy of seasonal influenza vaccination in children in Hong Kong: a randomized controlled trial**

**Authors:** Benjamin J. Cowling<sup>1</sup>, Sophia Ng<sup>1</sup>, Edward S. K. Ma<sup>2</sup>, Vicky J. Fang<sup>1</sup>, Teresa So<sup>1</sup>, Winnie Wai<sup>1</sup>, Calvin K. Y. Cheng<sup>1</sup>, Jessica Y. T. Wong<sup>1</sup>, Kwok-Hung Chan<sup>3</sup>, Dennis K. M. Ip<sup>1</sup>, Susan S. Chiu<sup>4</sup>, J. S. Malik Peiris<sup>2</sup>, Gabriel M. Leung<sup>1</sup>

**Affiliations:**

1. Infectious Disease Epidemiology Group, School of Public Health, Li Ka Shing Faculty of Medicine, The University of Hong Kong, Pokfulam, Hong Kong.
2. Centre for Influenza Research, Li Ka Shing Faculty of Medicine, The University of Hong Kong, Pokfulam, Hong Kong.
3. Department of Microbiology, Li Ka Shing Faculty of Medicine, The University of Hong Kong, Pokfulam, Hong Kong.
4. Department of Pediatrics and Adolescent Medicine, Li Ka Shing Faculty of Medicine, The University of Hong Kong, Pokfulam, Hong Kong Special Administrative Region, China.

### **Background:**

Seasonal influenza vaccination is most effective in preventing influenza infection and disease in healthy school-age children when circulating strains are similar to those included in the vaccine. The efficacy of seasonal influenza vaccination against 2009 pandemic influenza A(H1N1) remains unclear.

### **Objectives:**

To estimate the efficacy of 2009-10 Northern hemisphere seasonal trivalent inactivated influenza vaccine (TIV) in preventing influenza infection and illness in children.

### **Methods:**

A cluster-randomized trial in 796 households recruited between August 2009 and February 2010. One child aged 6-17 in each household was randomized to receive 2009-10 seasonal TIV or saline placebo. Sera were collected from all subjects at baseline, 1 month after receipt of vaccine and at the end of the study in August-December 2010, and from 25% of subjects in April-May 2010. Subjects and their household contacts reported acute respiratory illness episodes in daily symptom diaries and biweekly telephone follow-up, and home visits were arranged to collect respiratory specimens during illness episodes in any household members. The primary outcomes were influenza infection confirmed by reverse transcription polymerase chain reaction (RT-PCR) or serologic testing by hemagglutination inhibition assay.

**Results:**

Receipt of TIV rather than placebo led to 8-13 fold mean geometric rises in antibody titers against seasonal A and B viruses, but only 1.5-fold mean geometric rises against the pandemic A(H1N1) virus that was not included in the vaccine. Myalgia and local reactions at the injection site were more frequently reported following receipt of TIV than placebo, and no serious adverse events were reported. Compared to children who received placebo, children who received TIV had reduced risk of influenza B confirmed by RT-PCR with vaccine efficacy estimate of 65% (95% confidence interval, CI: 32%, 83%). Children who received TIV had reduced risk of influenza B and pandemic influenza A(H1N1) indicated by serology, with vaccine efficacy estimates of 86% (95% CI: 68%, 94%) and 52% (95% CI: 26%, 68%) respectively.

**Conclusions:**

Seasonal TIV prevented pandemic influenza A(H1N1) and influenza B infections in children. The potential mechanism for seasonal TIV to protect against pandemic A(H1N1) infection despite apparently poor immunogenicity deserves further study.