

**THE CHINESE UNIVERSITY OF HONG KONG**

*Department of Statistics*

will present a seminar entitled

**Statistical Challenges of Multiple Endpoints in Clinical Trials**

by

**Dr. Ivan S. F. Chan**  
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**West Point, Pennsylvania**

on

**Tuesday, 11 July 2006**  
**2:30pm – 3:30pm**

in

**Lady Shaw Building C2**  
**The Chinese University of Hong Kong**

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**Abstract:**

Clinical trials are frequently designed with many endpoints to measure benefits of a new treatment or vaccine. These endpoints are usually interrelated and designed to measure different aspects of the treatment outcome. When multiple endpoints are used to determine the success of study, a potential problem of drawing false positive conclusions exists. Appropriate adjustment for multiplicity is required to control the overall statistical error of making false positive claims. In this presentation, we will discuss the statistical challenges of multiple endpoints encountered in clinical trials. Then, we will present two novel approaches of handling multiple endpoints used in the clinical development of a herpes zoster (shingles) vaccine. The first approach is the use of a burden-of-illness (BOI) endpoint that measures the composite of incidence, severity and duration of herpes zoster. This BOI endpoint was used in a recently completed large-scale (N=38,546) efficacy trial of a shingles vaccine (Oxman *et al.* 2005, NEJM, 352, 2271-2284), which showed that the vaccine substantially reduced the risk of herpes zoster. In addition, the BOI endpoint increased the power of detecting a vaccine effect compared with the individual component endpoints. The second approach is a gate-keeping type strategy for controlling false positive rates associated with multiple families of endpoints. We will discuss its utility in the analysis and interpretation of the trial results about the shingles vaccine.

**All are Welcome**