

Department Seminars

Adaptive designs, treatment selection, and blinding in placebo-controlled randomized clinical trials

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Abstract:

In situations when many regimens are possible candidates for a large phase III study, but too few resources are available to evaluate each relative to the standard, conducting a multi-armed randomized selection trial is a useful strategy to remove inferior treatments from further consideration. When the study has a relatively quick endpoint such as an imaging-based lesion volume change in acute stroke patients, frequent interim monitoring of the trial is ethically and practically appealing to clinicians. In this talk, I will give a brief overview of adaptive design in clinical trials, and illustrate its advantage in terms of sample size in the context of treatment selection. Specifically, I will spend much time on a new class of sequential selection boundaries for multi-armed clinical trials, in which the objective is to select a treatment with a clinically significant improvement upon the control group, or to declare futility if no such treatment exists. The proposed boundaries are easy to implement in a blinded fashion, and can be applied on a flexible monitoring schedule in terms of calendar time. Design calibration with respect to prespecified levels of confidence is simple, and can be accomplished when the response rate of the control group is known only up to an interval. Some numerical results will be presented.

Bio:

Ken Cheung joined Columbia in 2000 after receiving his PhD in Statistics from the University of Wisconsin, Madison. His research interests include experimental design, with an expertise in the design and analysis of early phase clinical trials in cancer and neurological disorders.



SPECIAL SEMINAR

Tuesday,

July 8, 2008

140 Bardeen

2:00-3:00 p.m.