Biostats Workshop:

Non-Inferiority Design in Comparative Effectiveness Research: Should We be Bayesian for a While?

Samiran Ghosh (Associate Professor of Biostatistics, Wayne State University)

Thursday, January 17th, 1:30-2:50pm in MSOB x303

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Abstract:

Randomized controlled trials (RCT's) are an indispensable source of information about efficacy of treatments in almost any disease area. With the availability of multiple treatment options, comparative effectiveness research (CER) is gaining importance for better and informed health care decisions. However design and analysis of effectiveness trial is much more complex than the efficacy trial. The effect of including an active comparator arm/s in a RCT is immense. This gives rise to superiority and non-inferiority trials. The non-inferiority (NI) RCT design plays a fundamental role in CER, which will be also focus of this talk. In the past decade many statistical methods have been developed, though largely in the Frequentist setup. However, availability of historical placebo-controlled trial is useful and if integrated in the current NI trial design, can provide better precision for CER. This may reduce sample size burden and improves statistical power significantly in current trial. Bayesian paradigm provides a natural path to integrate historical as well as current trial data via sequential learning in the NI setup. In this talk we will discuss both fraction margin and fixed margin based Bayesian approach for three-arm NI trial. We will also discuss some interesting open problems related to CER using NI trial.

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