

BIOSTATISTICS SEMINAR



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Statistical Methods for Regulatory Tobacco Research

In 2009, Congress passed the Family Smoking Prevention and Tobacco Control Act which gave the Food and Drug Administration (FDA) the authority to limit the nicotine content of cigarettes to lower levels if such regulation would be likely to improve public health. The FDA has funded a variety of randomized controlled trials (RCTs) to investigate the effect of nicotine reduction on smoking behavior. However, there are a number of challenges with analyzing and interpreting data from these RCTs including (1) estimating the regulatory effect when noncompliance to randomized treatment assignment is reported with error; (2) understanding the effect in vulnerable subpopulations; and (3) synthesizing results from several medium-sized studies when there is treatment effect heterogeneity. In this talk, we present a suite of novel statistical methods to address these challenges. We apply our methods to data from recent clinical trials of very low nicotine content cigarettes conducted by the Center for the Evaluation of Nicotine Cigarettes (CENIC) at the University of Minnesota.

Joint work with Joseph S. Koopmeiners, Jeffrey A. Boatman, Ross L. Peterson, Ales Kotalik, and Chuyu Deng

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3:30 pm - 4:30 pm

Blue Cross and Blue Shield of North Carolina Foundation Auditorium



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