Title:
“Analysis of Medication Safety in a Longitudinal Observational Study”

Abstract:
The US Food and Drug Administration (FDA) issued separate warnings for suicidality with antidepressants and antiepileptic drugs in the past five years. Here two methods for examining the association of these agents with suicide attempts and suicide deaths are described using more broadly generalizable data than examined by the FDA. An observational study of mood disorders was examined that includes three decades of prospective assessments. Due to sample size differences, two distinct longitudinal implementations of the propensity adjustment are used in separate analyses of antidepressants and antiepileptic drugs. Propensity score quintile-stratified safety analyses were used with the large antidepressant data set; whereas, propensity score matched safety analyses were used with the smaller antiepileptic drug data because stratification was not feasible. In each case, mixed-effects survival models compared safety of participants when receiving the respective class of medication to periods when they did not receive that medication. When participants were more severely ill, they were significantly more likely to receive either class of psychotropics. Propensity quintile-stratified safety analyses found that risk of suicide attempts or suicides was significantly reduced when participants received antidepressants. In contrast, propensity score matched safety analyses found neither significant risk nor protection from suicidality among participants receiving antiepileptics.

Biography:
Andrew C. Leon, Ph.D. is Professor of Biostatistics in Psychiatry and Professor of Public Health at Weill Cornell Medical College and a DeWitt Wallace Senior Scholar at Weill Cornell. He specializes in quantitative issues in psychiatric research. His ongoing NIMH-funded research has developed and evaluated statistical techniques for treatment effectiveness analyses in longitudinal, observational studies. He is also examining methods of accounting for the problem of nonequivalent comparison groups in cluster randomized controlled clinical trials. He served as a member of the Psychopharmacologic Drugs Advisory Committee of the US Food and Drug Administration from 2002-2007. He testified before the US Congress, Committee on Veterans Affairs hearing Exploring the Relationship between Medication and Veteran Suicide in February, 2010. Dr. Leon is a member of the Executive Committee of the International Society of CNS Clinical Trials and Methodology (ISCTM). He is an Associate Editor of Statistics in Medicine and is on the Editorial Board of Journal of Clinical Psychiatry.

All are welcome to attend. No RSVP is required. Light refreshments will be served from 11.45am onwards, outside the auditorium.