PUBLIC HEALTH & PREVENTIVE MEDICINE

GRAND ROUNDS

Sponsored by: The Division of Biostatistics

Tom Greene, PhD
Professor
Division of Epidemiology
University of Utah

Thursday, March 15, 2012
12 PM-1 PM
MacHall 1162

Challenges in Validating Surrogate Endpoints: The Chronic Kidney Disease Experience

ABSTRACT

Randomized trials using a definitive clinical endpoint may be difficult to perform if the definitive endpoint is rare or does not occur until many years after patients are enrolled. This difficulty is particularly salient in studies of slowly progressing chronic diseases, where definitive clinical trials using hard clinical endpoints are often prohibitively long or require enrollment of an infeasible number of patients. As a result, much emphasis has been placed on efforts to identify and validate surrogate endpoints which may allow clinical trials to be performed using fewer patients and shorter follow-up periods. Unfortunately, a satisfactory concept of what it means to validate a surrogate endpoint has proven elusive, leading to much confusion and numerous false starts over the past 30 years. In this talk I will review the checkered history of the use of surrogate endpoints in randomized trials, and will examine associated confusions which have marred attempts to "validate" putative surrogates. I'll then overview three modern statistical approaches which have been advanced for the validation of surrogate endpoints, and will illustrate these approaches with an assessment of the validity of urine protein excretion as a surrogate endpoint in clinical trials of chronic kidney disease.

Food and beverages will be provided.

OREGON HEALTH & SCIENCE UNIVERSITY
OHSU