

The George Washington University
Department of Statistics
Fall 2005

SEMINAR ANNOUNCEMENT

Title: Augmented designs to assess immune response in vaccine trials

Speaker: Dean Follmann PhD
Assistant Director for Biostatistics, NIAID
Chief Biostatistics Research Branch
National Institute of Allergy and Infectious Diseases

Abstract: This paper introduces methods for use in vaccine clinical trials to help determine if the immune response to a vaccine is actually causing a reduction in the infection rate. This is not easy because immune response to the (say HIV) vaccine is only observed in the HIV vaccine arm. If we knew what the HIV-specific immune response in placebo recipients would have been, had they been vaccinated, this immune response could be treated essentially like a baseline covariate and an interaction with treatment could be evaluated. Relatedly, the rate of infection by this baseline covariate could be compared between the two groups and a causative role of immune response would be supported if infection risk decreased with increasing HIV immune response only in the vaccine group. We introduce two methods for inferring this HIV-specific immune response. The first involves vaccinating everyone before baseline with an irrelevant vaccine, e.g. rabies. Randomization ensures that the relationship between the immune responses to the rabies and HIV vaccines observed in the vaccine group is the same as what would have been seen in the placebo group. We infer a placebo volunteer's response to the HIV vaccine using their rabies response and a prediction model from the vaccine group. The second method entails vaccinating all uninfected placebo patients at the closeout of the trial with the HIV vaccine and recording immune response. We pretend this immune response at closeout is what they would have had at baseline. We can then infer what the distribution of immune response among placebo infecteds would have been. Such designs may help elucidate the role of immune response in preventing infections. More pointedly, they could be helpful in the decision to improve or abandon an HIV vaccine with mediocre performance in a phase III trial.

Date: Friday, October 28, 2005

Time: 4:00 pm - 5:00 pm

Location: Rome Hall (801 22nd Street NW), Room 351