

Biostat 578A: Evaluating Vaccine Efficacy

Questions for Readings 1

Due Thursday January 12

Assignment: Answer one of the following questions.

1. Rida and Lawrence (1994): What is the value of identifying a measurable immune response that predicts whether a vaccine recipient is protected from infection or disease? List several reasons why this is useful. In addition, think about potential challenges in finding such a “correlate of protection”, and list these challenges.
2. Hudgens, Gilbert, and Self (2004): Same question as for Rida and Lawrence (1994).
3. Flynn et al. (2005): Critique whether the analysis seems valid. Do you believe the results? What additional analyses would help inform on the potential utility of the tested vaccine?
4. Mehrotra, Li, and Gilbert (2006): Why are co-primary endpoints (HIV infection diagnosis and set-point viral load) used in the Merck/HVTN Phase IIb trial? What are some pros and cons of testing Merck’s vaccine in a Phase IIb trial versus in a larger (3 or 4 times more infections) Phase III trial?