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Biostatistics Seminars Winter 2021



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Vaccine Efficacy Trials for Emerging Pathogens

Wednesday, February 3, 2021
3:30 pm – 4:30 pm – [Zoom Link](#)

Abstract:

Rapid identification of a safe and effective vaccine for the prevention of COVID-19 is a critical public health goal. In this talk, I review the basic pathway for evaluating vaccines and describe the new 'pandemic paradigm' characterized by overlapping steps and greater up-front investment. Our group's research focuses on the optimal design of large Phase 3 clinical trials in the context of outbreaks. I discuss our prior work on Ebola vaccines and ongoing efforts as part of the WHO's R&D Blueprint for Action to Prevent Epidemics. Given the unpredictable spatiotemporal incidence of infectious diseases, we recommend that trials be flexibly designed to add new sites in a responsive manner, prioritizing areas with highest rates of disease. Site prioritization can be informed by ensemble forecast modeling. Furthermore, we recommend few large trials over many separate small trials. This collaboration speeds endpoint accrual, maximizes trial power, and makes the trial more robust to changing epidemiology.

Bio:

Dr. Natalie Dean is an assistant professor in the Department of Biostatistics at the University of Florida. She received her PhD in Biostatistics from Harvard. Her primary research area is infectious disease epidemiology and study design. She is principal investigator on an NIH R01 to develop and evaluate innovative trial and observational study designs for assessing the efficacy of vaccines targeting emerging pathogens. In 2015, she worked on an Ebola ring vaccination trial in Guinea, and is a member of the WHO's R&D Blueprint initiative's working group on clinical trials. Her current research focus areas are the use of outbreak modeling to inform vaccine trial designs, and the statistical properties of the test negative design.

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