

Statistical and mathematical details of trials for estimating vaccine effectiveness for emerging infectious disease threats: From Cholera to Ebola to COVID-19

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Room Benvenuti
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We are facing a global assault of emerging infectious disease threats. Some recent examples are Ebola, Zika, COVID-19, Lassa fever, mpox and chikungunya. When these threats emerge, there is an urgent need to evaluate the effectiveness of candidate vaccines as they are rolled out, first as experimental products with unknown effectiveness, and later in terms of optimal deployment for disease control.

In this presentation, we describe a model formulation to estimate the direct, indirect, total, and overall vaccine effects combining data from trials with two types of study designs: individual-randomization within cluster and cluster-randomization, based on a Cox proportional hazards model, where the hazard of infection depends on both vaccine status of the individual as well as the vaccine status of the other individuals in the same cluster. The estimating equations are derived as the partial likelihood score function for the marginal proportional hazards model. Then, the estimators for the vaccine effectiveness estimators are derived as functions of the estimated parameters.

We give applications for cholera, Ebola and COVID-19 vaccine trials.



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