Post-Randomization Factors, Direct Effects and Randomized Trials to Measure Risk Reductions

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Abstract

Randomization has been long used in therapeutic and intervention trials to form the basis of causal inference regarding treatment or intervention effects regarding risk reductions. The Methods for Improving Reproductive Health in Africa (MIRA) trial, designed to examine the effects of the diaphragm and lubricant gel in reducing sexually transmitted infection risk, raised issues regarding the standard intention-to-treat analysis due to the role of condom use during follow-up. A similar causal diagram arises in a very different situation involving blinded clinical trials with treatment-related side effects due to the potential for unmasking of treatment assignment. We will motivate and discuss these issues and discuss estimators of parameters based on definitions of the direct effect of the treatment/intervention of interest.

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