

Publication

Analysis of contamination in cluster randomized trials of malaria interventions

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BACKGROUND: In cluster randomized trials (CRTs) of interventions against malaria, mosquito movement between households ultimately leads to contamination between intervention and control arms, unless they are separated by wide buffer zones. **METHODS:** This paper proposes a method for adjusting estimates of intervention effectiveness for contamination and for estimating a contamination range between intervention arms, the distance over which contamination measurably biases the estimate of effectiveness. A sigmoid function is fitted to malaria prevalence or incidence data as a function of the distance of households to the intervention boundary, stratified by intervention status and including a random effect for the clustering. The method is evaluated in a simulation study, corresponding to a range of rural settings with varying intervention effectiveness and contamination range, and applied to a CRT of insecticide treated nets in Ghana. **RESULTS:** The simulations indicate that the method leads to approximately unbiased estimates of effectiveness. Precision decreases with increasing mosquito movement, but the contamination range is much smaller than the maximum distance traveled by mosquitoes. For the method to provide precise and approximately unbiased estimates, at least 50% of the households should be at distances greater than the estimated contamination range from the discordant intervention arm. **CONCLUSIONS:** A sigmoid approach provides an appropriate analysis for a CRT in the presence of contamination. Outcome data from boundary zones should not be discarded but used to provide estimates of the contamination range. This gives an alternative to "fried egg" designs, which use large clusters (increasing costs) and exclude buffer zones to avoid bias.

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