

Yale SCHOOL OF PUBLIC HEALTH

Biostatistics

Presentation

" Bayesian analysis of cluster randomized trials with multiple outcomes subject to truncation "

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ABSTRACT

In cluster randomized trials, the outcome measure for some study participants can become informatively truncated and unobservable due to death or drop-out. For instance, while quality of life (QoL) can still be well-defined for enrolled participants who drop out, they cannot be measured if enrolled participants die before the time of their measurement at the end of trial follow-up. In such cases, imputation methods that fill in QoL values for those who died may be conceptually unappealing to certain stakeholders when estimating treatment effects. While composite outcomes are popular solutions to account for death, they can be challenging to interpret and lack a clear causal interpretation. The survivor average causal effect (SACE) is an alternative estimand that surmounts some of these issues. Under the potential outcome framework, the SACE is defined as the average effect of the treatment on the non-mortality outcome among participants whose outcome would not be truncated by death under either treatment or control, that is, the principal strata of “always-survivors”. In this talk, we develop a Bayesian joint modeling approach to simultaneously estimate multiple SACEs with multivariate outcomes in cluster randomized trials. We differentiate the types of unobserved outcomes subject to death truncation and missingness due to drop-out and represent the observable outcomes through a mixture of multivariate linear mixed models. We combine the virtue of principal stratification and multilevel multiple imputation to address unobserved outcomes due to death and drop-out, while providing a clear causal interpretation for the treatment effects among the always-survivors. We carried out simulations to examine the finite-sample performance of the proposed approach to estimate multiple SACEs and different types of intraclass correlation coefficients with bivariate outcomes and provided a case study to

illustrate the application to the Whole Systems Demonstrator Telecare Questionnaire Study, a cluster randomized trial to improve the QoL among the elderly in the United Kingdom.

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