

Estimating Functions for Evaluating Treatment Effects in Cluster-Randomized Longitudinal Studies in the Presence of Drop-out and Non-compliance

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Abstract. We describe methods for analyzing longitudinal binary data from cluster randomized trials in which responses are incompletely observed and subjects may not be fully compliant with the prescribed treatment regimen. The method is based on a marginal regression model for the response where parameter estimates are obtained from generalized estimating equations. Estimating equations are also employed to estimate parameters of the missing data process which are used to compute inverse probability weights. A model is specified for the compliance process which facilitates estimating the expectation of the contributions to the estimating function for the response parameters among individuals without compliance data, which occurs when the control treatment involves no intervention. The approach is robust in the sense that semi-parametric models are used for the response and the missing data processes and robust variance estimates are advocated. The proposed method is shown to perform well in simulation studies, and data from a randomized trial of patients with depression are analyzed for illustration