

Yale SCHOOL OF PUBLIC HEALTH

Biostatistics

Presentation

" Sample size considerations for stepped wedge designs with subclusters "

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ABSTRACT

The stepped wedge cluster randomized trial (SW-CRT) is an increasingly popular design for evaluating health service delivery or policy interventions. An essential consideration of this design is the need to account for both within-period and between-period correlations in sample size calculations. Especially when embedded in health care delivery systems, many SW-CRTs may have subclusters nested in clusters, within which outcomes are collected longitudinally.

However, existing sample size methods that account for between-period correlations have not allowed for multiple levels of clustering. We present computationally efficient sample size procedures that properly differentiate within-period and between-period intracluster correlation coefficients in SW-CRTs in the presence of subclusters.

We introduce an extended block exchangeable correlation matrix to characterize the complex dependencies of outcomes within clusters. For Gaussian outcomes, we derive a closed-form sample size expression that depends on the correlation structure only through two eigenvalues of the extended block exchangeable correlation structure. For non-Gaussian outcomes, we present a generic sample size algorithm based on linearization and elucidate simplifications under canonical link functions. For example, we show that the approximate sample size formula under a logistic linear mixed model depends on three eigenvalues of the extended block exchangeable correlation matrix.

We provide an extension to accommodate unequal cluster sizes and validate the proposed methods via simulations. Finally, we illustrate our methods in two real SW-CRTs with sub clusters.

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