Cluster-Randomized and Quasi-Experimental Studies: Design and Analysis

RTI works closely with clients and collaborators to ensure the most practical and robust designs possible, both to minimize potential bias and to maximize generalizability. During data analysis, we use methodologies that account for clustering, and we collaborate with investigators to draw appropriate conclusions and interpret results in clear and meaningful language.

In research evaluations, the term *cluster* refers to any naturally occurring group of people that is the object of study. Examples include the following:

- Public health research on social and contextual factors that influence disease transmission among community members
- Evaluating the impact of a violence prevention curriculum on student victimization
- Health policy analysis on the efficiency of a new medical triage system for emergency room intake

Clustering is used for a variety of reasons. Often, the interventions of interest can be applied only to the larger social unit; for example, changes in community health practice, mass media messaging, tax policy changes, or whole school reform. At other times, there are ethical, practical, or logistical reasons for introducing interventions at the group level when we are interested in determining how they affect members of a group.

In clustered designs, interventions occur at the cluster level and measurements are collected at the individual level. Thus, measurements on individuals within the same cluster are expected to be correlated. This lack of independence, indexed by the intracluster correlation (ICC), reduces the amount of unique information and, by extension, the effective sample size. When clustering is ignored at the design stage, researchers risk fielding an underpowered study.

Ignoring clustering at the statistical analysis stage typically underestimates the true variability in the data and produces biased standard error estimates and misleading $p$-values. Commonly used analysis methods such as linear or logistic regression are likely to produce falsely high precision for the regression coefficients and confidence intervals that are too narrow (or $p$-values that are too small), leading to inaccurate conclusions.

RTI researchers use various methods to obtain preliminary estimates of the ICC on which to base sample size calculations at the study design stage, including literature reviews, pilot studies, and simulations. During the analysis stage, we adjust for clustering by employing appropriate statistical models, including (1) cluster-specific hierarchical or mixed models that incorporate additional variability and (2) a population-averaged generalized estimating equations (GEE) model, which extends regression to correlated data.
Project Experience


RTI conducted seven independent evaluations to assess the effectiveness of nutrition education programs in early child care centers, elementary schools, and senior centers serving predominantly low-income populations in the United States. Evaluation designs included assigning interventions to schools and centers and measuring program outcomes among participants nested within schools and centers. We worked with the state and local implementing agencies to determine appropriate sample size estimates and develop either cluster-randomized trials or quasi-experimental studies. We based analyses on the nested cohort design and employed hierarchical linear and generalized linear models. **Client: U.S. Department of Agriculture**

Impact Evaluation of a School-Based Violence Prevention Program (2004–2009). RTI designed this 5-year cluster-randomized study to assess the impacts of a school-based violence prevention program that included both curricular and whole-school reform components. The evaluation design included nested cross-sectional analyses of student populations and a nested cohort of high-risk youth who were tracked and surveyed annually. **Client: U.S. Department of Education**

The Study of Redesigned High Schools for Transformed STEM Learning in the North Carolina New Schools Project Network (2011–2015). This 4-year longitudinal research study of a sample of 10 redesigned science, technology, engineering, and mathematics (STEM) high schools has two main purposes: assess student learning over time and describe school-level policies and instructional practices that schools employ to promote student learning. The study has a quasi-experimental design, using a propensity-score-matching approach to identify comparison schools/students. **Client: National Science Foundation**


As the data coordinating center for the Global Network for Women and Children’s Health, RTI statisticians have worked with clinical investigators to design and implement several cluster-randomized community health trials in seven developing countries. These include the First Breath Trial, assessing the effects of a neonatal resuscitation training program on neonatal mortality; the First Bites Trial, assessing the effect of daily meat intake from 6 to 18 months of age on linear growth velocity; the Emergency Obstetric and Neonatal Care Trial, evaluating the impact of a comprehensive community/facility intervention on perinatal mortality; and the Antenatal Corticosteroid Trial, evaluating whether use of steroids at the community health center reduces neonatal mortality. The network also has a birth registry collecting baseline information used to generate ICC measures at both the community and facility levels that helped design these trials. Analysis methods include both linear mixed models (for continuous measures) and GEE models (for binary measures). **Client: The Eunice Kennedy Shriver National Institute of Child Health and Human Development**

More Information

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