Exercise 4: Sample Size Analysis for a Multilevel Study with Longitudinal Repeated Measures

4.1 Short Study Description

A multilevel study with longitudinal repeated measures.

4.2 Study vignette

The study described in this homework exercise is a strongly modified version of the one described in Komro et al. (2008). Modifications may include changing clustering, treatment design, number of measures, outcomes, predictors, time spacing, and all inputs for the power or sample size analysis, including means, standard deviations, sample sizes, powers, Type I error rates, correlations and covariates.

Scientists want to find a sample size for a planned randomized controlled clinical trial. They are interested in power of at least 0.90.

Researchers plan to conduct a randomized controlled clinical trial of an intervention designed to reduce adolescent alcohol use. The goal was to compare the intervention with no intervention. After obtaining consent from students, parents, teachers, and administrative staffs, researchers grouped schools within neighborhoods to form neighborhood groups. Neighborhood groups were randomized to either the alcohol use intervention or standard of care, using a 2 to 1 randomization scheme. The 2 to 1 randomization scheme has two times the number of neighborhoods randomized to the alcohol education program, as a result of community demand. For logistic and cost reasons, as well as the desire to ensure the smallest group is of sufficient size, the scientists wish to restrict total sample size to the range 30-45 neighborhoods.

Each student will be surveyed at baseline and again three more times after the treatment begins. Thus there will be four measurements, at baseline, in the spring of sixth grade, the spring of seventh grade, and the spring of eighth grade. The survey will use a detailed diet recall method to obtain an alcohol use scale for each student at each time point. Previous similar modeling with this variable has produced acceptably normally distributed jackknifed studentized residuals without transformation of the data.

For the purposes of this question, we can assume that there were an equal number of students in each classroom, an equal number of classrooms per school, and equal number of schools per neighborhood group.

We expect all neighborhoods, schools and classrooms to stay with the study throughout the entire time. However, we know that students move in and out of the district. Previous studies of student absences has reassured us that the absences of the students are not related to the neighborhood, classroom or school, nor to the use or non-use of the alcohol treatment program, nor to the age of the student.

There are 20 students in each classroom, with intracluster correlation of 0.09. There are 3 classrooms per school, with an intracluster correlation coefficient of 0.04. There are 2 schools per neighborhood, with an intracluster correlation coefficient of 0.03.

The researchers believe, from previous experience with similar data, that the correlation of scores across time followed a LEAR model with base correlation of 0.6 and a decay rate of 0.7, leading to a decrease in correlation of about 0.10 per unit time. The LEAR model (Simpson et al., 2010) allows correlation to be strong at first, and then die off with time at a rate controlled by the decay parameter. The AR(1) model is a special case.

Measurements will be conducted at 0, 6, 18 and 30 months. For the purposes of using GLIMMPSE, describe time values as 0, 1, 3 and 5 *HalfYears*. The scaling of the time values changes the LEAR correlation matrix due to the parameter structure chosen in GLIMMPSE.

Again from previous experience and work, the researchers are interested in the pattern of means in the following table.

Exhibit 1: Predicted neighborhood mean alcohol use scores stratified by treatment arm.

	Month 0	Month 6	Month 18	Month 30
Alcohol Education Program	5.2	5.3	5.3	5.3
Standard of Care	5.2	5.5	5.9	6.2

The common standard deviation is 4.

4.3 Statistical analysis plan

Scientists plan to fit a general linear mixed model with the alcohol use scores for each student as the outcomes. As predictors, they will use indicator variables for the two treatments, the alcohol education program and the standard of care. The scientists plan to account for correlation of schools within neighborhood groups, classrooms within schools, and students within classrooms. In all three levels, the schools are assumed to exchangeable within neighborhoods, the classrooms within schools, and the students within classrooms, leading to compound symmetry for each level of clustering, and a direct-product structure. The longitudinal repeated measures of alcohol use over time will assume a LEAR covariance structure (Simpson et al., 2010).

Scientists plan to use a Wald statistic with Kenward-Roger degrees of freedom (which corresponds to a Hotelling-Lawley Test for complete data), and a Type I error rate of 0.05 to evaluate the null hypothesis of no difference in pattern of average alcohol use scores over time between the treatments. The scale factor to be used for means is 1. The scale factor to be used for variability is 1.

References cited

Komro, Kelli A., Cheryl L. Perry, Sara Veblen-Mortenson, Kian Farbakhsh, Traci L. Toomey, Melissa H. Stigler, Rhonda Jones-Webb, Kari C. Kugler, Keryn E. Pasch, and Carolyn L. Williams. “Outcomes from a Randomized Controlled Trial of a Multi-Component Alcohol Use Preventive Intervention for Urban Youth: Project Northland Chicago.” *Addiction* (Abingdon, England) **103**, no. 4 (April 2008): 606–18. doi:10.1111/j.1360-0443.2007.02110.x.

Simpson, S. L., Edwards, L. J., Muller, K. E., Sen, P. K., & Styner, M. A. (2010). A linear exponent AR(1) family of correlation structures. *Statistics in Medicine*, **29**(17), 1825–1838. http://doi.org/10.1002/sim.3928