Design and Analysis of Community Trials in Epidemiology

PubH 6363
Syllabus

Spring Semester, 2007
Thursday  9:05-12:05  Mayo C-381
3 Credits

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Division of Epidemiology and Community Health
1300 South Second Street #300
Design and Analysis of Community Trials in Epidemiology

Purpose: This course provides instruction in the design and analysis of group-randomized trials (GRTs) in epidemiology including the characteristics of GRTs, and their statistical, practical, and ethical issues.

Target Audience, Prerequisites: The course is designed for advanced students in health related fields who plan to pursue a career in research. Course work in statistics covering analysis of variance and multiple regression is required (e.g., PubH 6450, 6452, 6454; PubH 6341). An introductory course in research design would be helpful (e.g., PubH 6806 or 6852).

Learning Objectives: Students will be able to:
1) discuss the purposes of group-randomized trials in epidemiology;
2) define the terminology used to describe their research designs;
3) explain the components of group-randomized trials including specification of the research question and selection of the proper design, measures, study populations and analysis procedures;
4) describe the factors that affect the validity of these trials;
5) explain the strengths and weaknesses of several design alternatives;
6) critique existing trials;
7) discuss the strengths and weaknesses of several analysis alternatives;
8) select an appropriate analysis for a particular design; and
9) employ suitable computer software to analyze data from group-randomized trials.

Students who complete this course should be better able to plan, to analyze, and to critically review group-randomized trials in epidemiology, as well as being aware of the difficulties of implementing a GRT.

Methods of Instruction: The course uses practically all of the textbook (Murray, 1998), with some extra material for extending discussion of some topics. Hence, students will have the resources in hand and will be expected to preview as well as going over material covered by presentation and discussion in class-time. Throughout the course assignments of scientific papers reporting on GRTs will be given to expose students to such literature and to give practice in critical review; students will be expected to provide summaries from reading the paper and to be able to summarize the salient points in the paper. Homework assignments will give the students practice in applying the analytic methods presented in class to data from group-randomized trials. By meeting in the computer laboratory students will have hands-on experience of running analyses of GRTs using the same dataset as used by Murray.
**Required Text:**


Highly recommended as a complementary volume is


Other statistical resources that the student might like to explore:

- Anthony S Bryk and Stephen W. Raudenbush (1992), Hierarchical Linear Models, Newbury Park:Sage. *(The authors come from the educational field so the language is different, but the hierarchical formulation of models involving multiple sources of variance is quite readable and complements the textbook).*
- Murray DM, Hannan PJ, Wolfinger RD, Baker WL and Dwyer JH (1998), Analysis of data from group-randomized trials with repeat observations on the same groups. Stats. in Medicine 17:1581-1600
- Hannan PJ and Murray DM (1996), Gauss or Bernoulli? A Monte Carlo comparison of the linear mixed model and the logistic mixed model analyses in simulated community trials with a dichotomous outcome variable at the individual level, Evaluation Review 20(3):338-352
Disability/Accessibility Statement

Any student with a documented disability (e.g., physical, learning, psychiatric, vision, hearing, etc.) who needs to arrange reasonable accommodations must contact the instructor and Disability Services at the beginning of the semester. All discussions will remain confidential. For further information contact the University of Minnesota Disability Services website at: [http://ds.umn.edu](http://ds.umn.edu) or call 612/626-1333 (V/TTY).

Grading Criteria –

S/N option must complete all assignments to a C level (73%).
Letter grade will be determined by total effort as follows:

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<th>70-72</th>
<th>73-76</th>
<th>77-79</th>
<th>80-82</th>
<th>83-86</th>
<th>87-89</th>
<th>90-94</th>
<th>95-100</th>
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<td>C-</td>
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<td>C+</td>
<td>B-</td>
<td>B</td>
<td>B+</td>
<td>A-</td>
<td>A</td>
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F (or N) – Represents failure (or no credit) and signifies that the work was either (1) completed but at a level of achievement that is not worthy of credit or (2) was not completed and there was no agreement between the instructor and the student that the student would be awarded an I (for incomplete).

S – Achievement that is satisfactory will be expected to complete all assignments and receive a minimum of 73% to receive a passing score.

I – An incomplete grade ("I") is permitted only in cases of exceptional circumstances and following consultation with the instructor. In such cases, an "I" grade will require a specific and written contract with the instructor for timely completion of remaining assignments. Additionally, some majors in the School of Public Health may place a hold on a student’s registration until an “I” is cleared up, or a plan for completion of the work submitted.

Students may change grading options without written permission as specified by the University and without penalty during the initial registration period or during the first two weeks of the semester. The grading option may not be changed after the second week of the term.

School of Public Health students may withdraw from a course through the second week of the semester without permission. No “W” will appear on the transcript.

After the second week students are required to do the following:

1. The student must contact and notify their advisor and course instructor informing them of the decision to withdraw from the course.
2. An email must be sent to the SPH Student Services Center (SSC) from the student. The email must provide name, ID#, course number, section number, semester and year with instructions to withdraw from the course, and acknowledgement that the instructor and advisor have been contacted.
3. The advisor and instructor must email the SSC acknowledging the student is canceling the course. All parties must be notified of the student’s intent.
4. After the SSC receives all emails (student, advisor, instructor) the SSC will complete the process by withdrawing the student from the course. A “W” will be placed and remain on the student transcript.

After discussion with their advisor and notification to the instructor, students may withdraw up until the eighth week of the semester. There is no appeal process. For more information, contact the SPH Student Services Center at 612.626.3500.

A refund schedule for tuition and fees is listed in the University class schedule. Please refer to these dates when withdrawing from courses.

**Scholastic dishonesty and plagiarism**

Students are responsible for knowing the University of Minnesota, Board of Regents' policy on student conduct and scholastic dishonesty:

http://www1.umn.edu/regents/policies/academic/Student_Conduct_Code.html

Scholastic dishonesty as defined in the policy and will be reported to the Office of Student Judicial Affairs and will result in a grade of "F" or "N" for the entire course.

*Plagiarism* is an important element of this policy. It is defined as the presentation of another's writing or ideas as your own. Serious, intentional plagiarism will result in a grade of "F" or "N" for the entire course. For more information on this policy and for a helpful discussion of preventing plagiarism, please consult University policies and procedures regarding academic integrity: http://cisw.cla.umn.edu/plagiarism/uofmpolicies.html.

Students are urged to be careful that they properly attribute and cite others' work in their own writing. For guidelines for correctly citing sources, go to http://tutorial.lib.umn.edu/ and click on "Citing Sources".

In addition, original work is expected in this course. It is unacceptable to hand in assignments for this course for which you receive credit in another course unless by prior agreement with the instructor. Building on a line of work begun in another course or leading to a thesis, dissertation, or final project is acceptable.

If you have any questions, consult the instructor.
Evaluation and Grading: Evaluation will be based on class participation and homework assignments throughout the course (20%), a take-home midterm exam being a critique of two selected GRT papers (30%), and a final being the data section (measurement, design, power, analysis, critique) of a proposal (50%). Students are expected to participate actively in each class and must remain current in their readings throughout the quarter in order to participate fully. Students must achieve at least 2/3 of the marks (67%) in each of the three types of evaluation to be considered for a pass.

The midterm will be take-home, open-book exam. The midterm will be available at the end of the 9th class (Thursday March 22 2007) and due at the beginning of the 10th class (9:05am Thursday March 29 2007). Students will be asked to read one or more journal articles or other research material and to answer questions about the methods and findings presented. The exam will require more than one day to complete. It is designed both as a means of evaluation and as an intensive learning experience.

For the final, the students will be required to analyze and ‘write-up’ results from the provided data in a format akin to a formal research paper. The student is to write the data section, with focus on the research design, variables of interest and their measures, analysis methods, power analysis, and limitations. It will be about 10-15 pages double-spaces, plus tables and figures.

Classroom performance on assigned papers will be by agreement between the instructors, and on homework will be graded by one or other of the instructors. Midterm and final will be a consensus grade arrived at by the two instructors. Letter grades or S/N grades are available. A grade of "C" or higher is needed for an "S."

Written assignments are expected to be typed, including mathematical equations, and submitted in PDF format.
Other Readings - these may very well change for Spring Semester 2007

Papers assigned for homeworks may be from these or other papers


Hierarchical Linear Models and SAS proc MIXED – two approaches to the same problem

Parts of Singer’s article will be used to complement the material in Murray’s textbook.

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<tr>
<th>#</th>
<th>Date</th>
<th>Objectives</th>
<th>Part I</th>
<th>Part II</th>
<th>Chapters</th>
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<tr>
<td>1</td>
<td>1/18</td>
<td>Counterfactuals, experimental and observational designs; Groups.</td>
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<td>Introduction to SAS &amp; Stata</td>
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<td>2</td>
<td>1/25</td>
<td>Designs, bias and threats to useful inference (eg, SUTVA)</td>
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<td>Regression in SAS &amp; Stata</td>
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<td>3</td>
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<td>Measures and measurement, precision</td>
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<td>GLAMM</td>
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<td>4</td>
<td>2/08</td>
<td>Nested XS – Post-test only (OLS and mixed)</td>
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<td>Computer lab exercises</td>
<td>5</td>
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<tr>
<td>5</td>
<td>2/15</td>
<td>Nested XS – Post-test only; adjusted means</td>
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<td>Computer lab exercises</td>
<td>7</td>
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<td>6</td>
<td>2/22</td>
<td>Nested XS – Pre/Post analysis</td>
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<td>Computer lab exercises</td>
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<td>7</td>
<td>3/01</td>
<td>Nested XS – Pre/Post analysis</td>
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<td>3/08</td>
<td>Special Lecture: Prof Stefanie Deluca Johns Hopkins</td>
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<td>Spring Break</td>
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<td>9</td>
<td>3/22</td>
<td>Nested Cohort – Pre/Post modeling and analysis</td>
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<td>Computer lab exercises</td>
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<td>10</td>
<td>3/29</td>
<td>Nested Cohort – Pre/Post modeling and analysis</td>
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<td>Computer lab exercises</td>
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<tr>
<td>11</td>
<td>4/05</td>
<td>Statistical power, minimum detectable effect</td>
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<td>Computer lab exercises</td>
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<td>12</td>
<td>4/12</td>
<td>Design and implementation of interventions</td>
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<td>13</td>
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<td>Advanced analyses: permutation tests, RC, etc</td>
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<td>Computer lab exercises</td>
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<td>14</td>
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<td>Grant writing &amp; ethics</td>
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<td>15</td>
<td>5/03</td>
<td>Review and wrap up</td>
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Chapter s refer to the text *Design and Analysis of Group-Randomized Trials* (Murray, 1998) Oxford U.P.