BIOSTATISTICS 699
DESIGN AND ANALYSIS OF BIOSTATISTICAL INVESTIGATIONS
Winter Term 2014
Tu, Th 1:00pm - 3:00pm (NO MICHIGAN TIME)

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Office Hours: TBA  Office Hours: TBA

Location: M1112 SPH II (and M1123 when there are interim and final presentations)

Course Objectives:
The overall objective of this course is to help the student integrate and apply biostatistical
methods presented in Master’s level courses. The student will learn to identify the scientific
objectives of a study and to develop a statistical strategy appropriate for those objectives. The
student will learn to plan strategies for statistical design and analysis and to implement these
strategies. The student will integrate methods learned in various courses during the analysis of
multi-faceted projects. The student will learn to be aware of problems that arise in study design,
power and sample size determination and data collection. The student will learn to communicate
through presentation of oral and written reports, and through student and faculty critiques of
these reports at both the intermediate and final stages of projects.

Biostatistics Competencies:
1. Describe the roles biostatistics serves in the discipline of public health.
2. Describe preferred methodological alternatives to commonly used statistical methods when
   assumptions are not met.
3. Distinguish among the different measurement scales and the implications for selection of
   statistical methods to be used based on these distinctions.
4. Apply descriptive techniques commonly used to summarize public health data.
5. Apply common statistical methods for inference.
6. Apply descriptive and inferential methodologies according to the type of study design for
   answering a particular research question.
7. Interpret results of statistical analyses found in public health studies.
8. Develop written and oral presentations based on statistical analyses for both public health
   professionals and educated lay audiences.

Organization of Class:
The 4 hours per week will be divided among:
1) Presentation and initial discussion of projects (led by faculty or visiting presenters).
2) Presentation of intermediate and final results of projects (led by students).
3) Discussion of problems that arise in the design and analysis of biostatistical investigations
   (led by faculty).
4) Review and discussion of articles with statistical applications (led by students).
5) Discussion of topics in statistical methodology (led by faculty).

Students will be expected to:
1) Critique and discuss journal articles selected by faculty.
2) Present intermediate and final written and oral reports of analyses.
3) Participate actively in classroom discussions of projects and articles.
Journal Article Readings and Presentations:
Students will be put in groups of 4 members each, and each group will be assigned one paper from a journal in the medical or biological literature. Each student group will lead the class discussion of their assigned application paper. The goal of the discussion will be to critique the appropriateness of the statistical analysis for the primary hypotheses of interest in the paper and the statistical soundness or limitation of the findings in the article. Presentations will be approximately 20 minutes followed by a 10-minute discussion. Copies of the articles will be distributed and all students are to read each paper before it is presented in class. These presentations will occur simultaneously with the major analysis projects and will be scheduled by the instructors.

Projects:
There will be five projects throughout the semester. Note that due to time constraints, successive projects will overlap slightly with each other. Each project will span 7-8 class periods and will have the following timeline:

(i) A scientific investigator with little or no experience with statistical analysis, will attend class and introduce the scientific objectives for the project. During this presentation and later class periods, students are expected to ask questions in order to develop a relevant statistical approach for the project and to collaborate with the scientist in the definition and formalization of the statistical objectives of the project. The scientific investigator will be available for questions at the initial presentation; the instructors will act as the scientific investigator in subsequent class periods.

(ii) About 3-4 class periods later, half of the students will give a 10-minute interim presentation covering the preliminary stages of their investigation with slides formally created with Microsoft PowerPoint, LaTeX, or other software. This interim report will include a description of the problem, objectives, hypotheses, models (equations), proposed tables and diagnostics, an interim report of analyses already performed, and any identification of questions that may have been raised by the analysis. Each student giving an interim presentation must turn in a copy of their oral report to the instructors. All students are expected to thoroughly discuss the issues raised in each presentation.

(iii) About 3-4 additional class periods later, the remaining half of the students will give a 10-12 minute final presentation with slides formally created with Microsoft PowerPoint, LaTeX, or other software and will provide a copy of this presentation to the instructors.

(iv) All students, regardless of type of report (interim or final), will hand in a final written report for each project. Late reports will not be allowed except in special circumstances and with the approval of the instructors.

(v) Projects 1 and 5 will differ from the other three projects. Whereas students will work individually in Projects 2-4, students will work in pairs assigned by the instructors for Projects 1 and 5. For Project 1, each pair will give a single interim and a single final oral presentation. For Project 5, each pair will give a single interim oral presentation followed by a single final poster presentation (in lieu of a final oral presentation). Furthermore, each pair will prepare a single written report for Projects 1 and 5. The report should include an explanation of what each member of the pair contributed in a section called Author Contributions.
Written reports are to be printed double-spaced and are limited to a maximum of six pages of text (excluding tables and supporting output). Reports and computer output must be produced on a laser or Xerox printer using a clean dark font. The written report should use language appropriate for a medical journal (e.g. NEJM) and should include the following:

a) **Title**, date, and student identifier (last 4 digits of student id). Student names must not be used.

b) **Abstract** or executive summary (half page): A summary of the main findings.

c) **Introduction**: A short description of the problem (1-2 paragraphs)

d) **Statistical Methods**: This description can include technical language and equations. It may be appropriate to intersperse the methods with the results section if there are several distinct parts to the analysis. A listing of the commands used to produce the major analyses should be included as an appendix.

e) **Results**: May include any of the following: summary statistics of the data, description and interpretation of the fitted models and parameters estimated, the values of estimates, hypotheses tested, relevant inferences (e.g. probabilistic inferences such as confidence intervals, \( p \)-values), and tabular and graphical representation of the results. Appendices should include analysis results documenting the details of your analyses, such as evaluating the validity of the assumptions or models used in the analysis, even if these details are not included in the written report. Tables and figures that are of major relevance to the main aims of the project should be placed in the main text. Tables and figures that are not directly linked to the main goals of the project should be placed in the Appendix. References in the main report to tables, graphs, and computer output in the Appendix should identify the relevant pages. Tables and graphs should be clearly labeled and numbered, but need not be of presentation quality.

f) **Conclusions** (1 to 3 paragraphs): Descriptions of the scientific conclusions that can be drawn from the analysis results; unanswered questions needing additional study may be included. This section should directly relate the performed analyses to the scientific question addressed.

**Training in human subject research:**
All students are required to take the UM PEERRS online training available at [http://my.research.umich.edu/peerrs/help.php#getstarted](http://my.research.umich.edu/peerrs/help.php#getstarted)
All students should obtain certification in the four modules

- **Foundations of Good Research Practice**
- **Conflict of Interest**
- **Human Subjects - Biomedical & Health Sciences**
- **Authorship, Publication and Peer Review**

**Final grade:**
The final grade will be determined by the quality of the oral and written reports and by the participation and leadership of the student in classroom discussions. Both technical content and the presentation of that content are important (e.g. organization and clarity of language). The first project will be down-weighted as it is considered as an initial learning exercise. Active participation in class discussions is important for success in the class.

The following will be considered in the final evaluation:

1. Quality of the technical and statistical aspects of the analyses of the projects (approx 40%).
2. Quality of the written presentations of projects (organization, completeness, clarity, and conciseness) (approx 40%).
3. Quality of the oral presentation of projects, scientific papers, and discussions, specifically related to identifying and summarizing the major issues (approx 10%).
4. Class participation (approx 10%).
SPH Policy Statement on Academic Integrity

The faculty of the School of Public Health believes that the conduct of a student registered or taking courses in the School should be consistent with that of a professional person. Students should show courtesy, honesty, and respect toward faculty members, guest lecturers, administrative support staff, and fellow students. Similarly, students should expect faculty to treat them fairly, showing respect for their ideas and opinions and striving to help them achieve maximum benefits from their experience in the School. Student academic misconduct refers to behavior that may include plagiarism, cheating, fabrication, falsification of records or official documents, intentional misuse of equipment or materials (including library materials), and aiding and abetting the perpetration of such acts. The preparation of reports, papers, and examinations, assigned on an individual basis, must represent each student's own effort. Reference sources should be indicated clearly. The use of assistance from other students or aids of any kind during a written examination, except when the use of aids such as electronic devices, books or notes has been approved by an instructor, is a violation of the standard of academic conduct.
Tentative Class Schedule (D=Description; I=Interim Presentation; F=Final Presentation)

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Tom Braun out-of-town    Mike Elliott out of town