

BIostatISTICS 699
DESIGN AND ANALYSIS OF BIostatISTICAL INVESTIGATIONS

Winter Term 2019
Tu, Th 1:00pm - 3:00pm

Instructors:

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Location: 1755 SPH I (and M1122 and M1152 SPH II when there are student presentations).

Course Objectives:

The overall objective of this course is to help students 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 3 or 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:

(a) 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.

(b) About 3-4 class periods later, half of the students will give an 8-10 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.

(c) About 3-4 additional class periods later, the remaining half of the students will give an 8-10 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.

(d) 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.*

(e) 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 & final project). Each pair will prepare a single written report for Project 1. The report should include an explanation of what each member of the pair contributed in a section called Author Contributions.

(f) 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:

- 1) **Title**, date, and student identifier (last 4 digits of student id). Student names **must not** be used.
- 2) **Abstract** or executive summary (half page): A summary of the main findings.
- 3) **Introduction**: A short description of the problem (1-2 paragraphs)
- 4) **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.
- 5) **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.
- 6) **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/#requirements>

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 project analyses (approximately 40%).
2. Quality of the written presentations of projects (organization, completeness, clarity, and conciseness) (approximately 40%).
3. Quality of the oral presentation of projects, scientific papers, and discussions, specifically related to identifying and summarizing the major issues (approximately 10%).
4. Class participation (approximately 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.

Student Well-Being:

SPH faculty and staff believe it is important to support the physical and emotional well-being of our students. If you have a physical or mental health issue that is affecting your performance or participation in any course, and/or if you need help connecting with University services, please contact the instructor or the Office of Academic Affairs.

Please visit <http://sph.umich.edu/student-life/wellness.html> for information on wellness resources available to you.

Student Accommodations:

Students should speak with their instructors before or during the first week of classes regarding any special needs. Students can also visit the Office of Academic Affairs for assistance in coordinating communications around accommodations.

Students seeking academic accommodations should register with Services for Students with Disabilities (SSD). SSD arranges reasonable and appropriate academic accommodations for students with disabilities. Please visit <https://ssd.umich.edu/topic/our-services> for more information on student accommodations.

Students who expect to miss classes, examinations, or other assignments as a consequence of their religious observance shall be provided with a reasonable alternative opportunity to complete such academic responsibilities. It is the obligation of students to provide faculty with reasonable notice of the dates of religious holidays on which they will be absent. Please visit http://www.provost.umich.edu/calendar/religious_holidays.html#conflicts for the complete University policy.

Diversity, Equity, and Inclusion (DEI):

At SPH, our mission to promote population health worldwide is inseparable from our aim to develop more effective and socially just systems for creating and disseminating knowledge. As part of this, we recognize the historical and contemporary expressions of social discrimination globally, and seek to promote and extend opportunities for members of all groups experience such marginalization. We commit to developing the institutional mechanisms and norms necessary to promote the values of diversity, equity, and inclusion, both inside and outside our classrooms. To this end, SPH upholds the expectations that all courses will (1) **be inclusive**, (2) **promote honest & respectful discussions**, (3) **follow multicultural ground rules** and (4) **abide by UM policies and procedures**.

- 1) **Inclusive courses**, are those in which teachers and learners co-create and co-sustain environments that support and encourage all members to participate equitably. See <http://crlt.umich.edu/multicultural-teaching/inclusive-teaching-strategies> for more resources.
- 2) **Honest & respectful** (rather than safe) discussions promote diversity and social justice learning by acknowledging dynamics of oppression and privilege both inside and outside the classroom. Read more at

<http://ssw.umich.edu/sites/default/files/documents/events/colc/from-safe-spaces-to-brave-spaces.pdf>.

- 3) **Multicultural ground rules** acknowledge diverse experiences in the classroom and offer strategies for holding one another appropriately accountable. See examples from the UM Program on Intergroup Relations and others at <http://ncdd.org/rc/item/1505>.
- 4) **UM policies and procedures** can be found at <http://diversity.umich.edu> with additional resources and instructions for reporting discrimination at <https://sph.umich.edu/diversity-equity-inclusion/resources.html>.