Syllabus: M17-5881, Summer 2017

Analysis of Clinical Data

About the Coursemaster

Contact Information:

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Preferred method of contact: e-mail
In-Person Office Hours: by appointment

Welcome: Welcome to Analysis of Clinical Data. My name is Dorina Kallogjeri and I am your instructor for this course. I hope that you are as excited as I am to explore more complex usage of statistics in medicine, and I look forward to meeting you all. This course is designed to build basic skills in Statistics for clinical research. For those continuing on in the yearlong program, this course will have you prepare for the fall course Introductory Statistics for the Health Sciences and to foster basic expertise required to independently use common multivariate biostatistical methods to analyze clinical research data for peer-review presentation and publication.

Coursemaster Biography: I obtained my medical degree (MD) from University of Tirana, Albania, and an MPH (Biostatistics and Epidemiology) from St. Louis University. I have over 14 years of experience in clinical research with a special interest on prediction models and clinical outcomes. I currently serve as the Research Statistician for the Department of Otolaryngology at Washington University, and I provide consulting services for researchers in other departments at Washington University. I am also the statistical editor for JAMA Otolaryngology-Head and Neck Surgery.

During my research career, I have participated in almost all aspects of a research project, from basic data entry to writing large RO1 grants. I try to bring this breadth of experience with me into my classroom, in order to help my students better understand clinical statistics from a practical point of view.

I am the Coursemaster for the introductory-and intermediate-level medical statistics courses taught as part of the Master of Science in Clinical Investigation (MSCI) at the Clinical Research Training Center. In addition, I teach “Introduction to Statistics and Research Methods” to audiology students enrolled in the Program in Audiology and Communication Sciences. In my courses, I teach statistical concepts and model-building as applied to the clinical research field.
Teaching Philosophy:

The core of my teaching philosophy is that as students in my class, you develop the knowledge and skills that will allow you to feel comfortable using, evaluating, and continuing to learn about statistics throughout your careers as healthcare professionals. Statistics is a beautiful and powerful part of medicine, and I use my medical education and years of teaching experience to give insights into this wonderful field. My lectures are designed to expose you to important theoretical concepts, while adding nuance and understanding with examples and real life applications. Equally as important as the lectures are the practical portions of the course. I will introduce different examples and exercises for each of the topics covered in class. In addition I will demonstrate analysis of real life datasets and the interpretation of results in a format that is clinician friendly. Learning statistics is all about doing statistics. Problem sets are planned to expose you to analysis of concepts covered in class.

I have a passion for this field, and I am always available for questions, either about the course material or statistical concepts in general. I am also happy to suggest further reading for students who are interested in more advanced statistical techniques. Finally, I hope that at the end of this course, you will emerge as a better clinical researcher, and will be able communicate better and more efficiently with a statistician and with the rest of the research team.

About This Course

Required Texts:
Discovering Statistics Using IBM SPSS Statistics by Andy Field, 4th edition. (Sage 2013). (CRTC will loan you this book for the summer)

Other Course Materials:
IBM SPSS Statistics software will be provided. Look for an e-mail from Jessica Chafe ichafe@wustl.edu or Rachel Sorensen r.sorensen@wustl.edu with details on how to download and install SPSS. This software is also available on the computers in the CRTC computer bays.

Course Description:
This 5 day course consists of 5 lectures followed by 5 laboratory sessions using 5 different clinical research datasets. The clinical research datasets to be analyzed are each associated with a peer-reviewed publication from a high-quality academic journal. Through reading and brief critical appraisal of the articles, students will be guided to discuss main Evidence Based Medicine (EBM) criteria for review of articles in the medical field. Each lecture will present basic statistical concepts and methods used in data preparation (manipulation) and data analysis of a research project. Data management will be discussed in the context of each project (session) with the purpose of teaching students the main concepts of data management needed for a research project as part of a research lab. Each article (each session) also introduces a new method for multivariate analysis of data, and will be part of the demonstration by the instructor only with the goal of providing the full picture of the analysis done within a project.

This course will equip students with the basic expertise needed to investigate and describe data and basic relationships between variables in a dataset. During each laboratory session students will be analyzing datasets used for each of the articles and summarize their findings.

This class places the students in the seat of a researcher and walks them through the logical and practical steps of a standard research project from generation of a research idea (identifying study’s main objective and specific aims) to drawing conclusions based on hands-on data analysis. The course, in conjunction with other coursework focusing on clinical research design, and scientific writing, will help students to better understand the clinical research field and learn to apply the obtained knowledge in real life projects.

This is a hands-on course that illustrates basic concepts and basic statistical tests. Students will work with IBM SPSS statistics version 23. IBM SPSS is a user-friendly statistical software package. The best way to learn statistics is by doing statistics.
Goals of the Course:
By the end of this course the student should be able to:

- Effectively use IBM SPSS statistics to select and perform a variety of data management techniques, data description and main tests of bivariate analysis.
- Understand how to interpret the results of the above mentioned analysis.
- Identify key EBM criteria for critical review of manuscripts.

Course Schedule (subject to modification)

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<thead>
<tr>
<th>Dates</th>
<th>Topic</th>
<th>Readings Due</th>
<th>Assignments Due</th>
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<tbody>
<tr>
<td>June 6 1:00-4:00pm</td>
<td>Module 1: P.C.A Louis and the Birth of Clinical Epidemiology</td>
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<tr>
<td>June 12 1:00-4:00pm</td>
<td>Module 2: Growth and Development in Children with sickle-cell trait</td>
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<tr>
<td>June 16 1:00-4:00pm</td>
<td>Module 3: Variability in Radiologists’ interpretations of Mammograms</td>
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<tr>
<td>June 19 1:00-4:00pm</td>
<td>Module 4: New Clinical Staging System for Cancer of the Larynx; 5-year survival rates</td>
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<td>It is required that you read the article and prepare the critical appraisal for each Module prior to class.</td>
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<tr>
<td>June 22 1:00-4:00pm</td>
<td>Module 5: Prognostic Importance of Comorbidity in a Hospital-Based Cancer Registry</td>
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Assessment/Grading

Grade Composition:
This is a pass/fail course. To pass the course, each student must adhere to the attendance policy outlined below, commit full-time effort to the program, and complete all assignments in a timely manner as dictated by the course instructors.

Attendance Requirement:
Class participation is a vital part of ASPIRE. Students are expected to physically attend at all five (5) sessions. Students whose circumstances prevent them from meeting this program attendance requirement must receive prior written approval of the instructor, and agree on an alternate plan to achieve course objectives and earn academic credit. Students must notify the instructor and Jessica Chafe, jchafe@wustl.edu, in advance if they will be missing a session of class.

Technical Support

If you have any technical problems accessing Blackboard please e-mail crtc@email.wustl.edu. Note, this mailbox is not monitored in the evening or on weekends. If you need immediate help after hours please put a service request into https://wusm.service-now.com.

Course Policies

Participation (Expectations):
- It is vitally important that our classroom environment promote the respectful exchange of ideas. This entails being sensitive to the views and beliefs expressed during discussions whether in class or online.
- Your success in this course will heavily depend on your ability to communicate, engage and participate in all course activities. Successful completion of this course requires that a student keep up with all assignments and prep work for the lab components.
If you are unable to participate in the scheduled class activity or discussions you must notify the coursemaster within the week of that class module or discussion. An unexcused failure to engage or participate with the class will be counted as an absence; unexcused absences may result in failure. The coursemaster reserves the right to make judgment to accept and/or make–up assignments missed because of failed participation in the course activities.

**Drop Dates:**
If the occasion should arise that you want or need to drop this class, please see me first. You can drop for any reason during the course of the semester, however you may only receive a partial or no tuition reimbursement depending upon how far into the semester you drop the course. See the Academic Calendar for your program for specific dates and reimbursement policies. Note, late withdrawals will also appear on your transcript as a withdrawal.

**CRTC Academic Policy Guidelines:**
Guidelines regarding CRTC course registration and enrollment, grades, tuition obligation, and academic leave are consolidated in the CRTC Academic Policy Guidelines. Please take a moment to review this document.

**CRTC Guidelines for Academic and Non-Academic Transgressions:**
By registering for this course you have agreed to the terms of the CRTC Guidelines for Academic and Non-Academic Transgressions. If you have not already reviewed this policy, please be sure to before beginning any CRTC related coursework.

**Academic Integrity/Plagiarism:**
- Academic dishonesty is a serious offense that may lead to probation, suspension, or dismissal from the University. One form of academic dishonesty is plagiarism – the use of an author’s ideas, statements, or approaches without crediting the source. Academic dishonesty also includes such acts as cheating by copying information from another student. **Plagiarism and cheating are not acceptable.**
- Academic dishonesty will be reported to the Office of the Registrar for possible action. The coursemaster will make an academic judgment about the student’s grade on that work and in that course. The CRTC process regarding academic dishonesty is described in the CRTC Guidelines for Academic and Non-Academic Transgressions.

**Writing Assistance:**
For additional help on your writing, consult the expert staff of The Writing Center in Olin Library (first floor). It can be enormously helpful to ask someone outside a course to read your essays and to provide feedback on strength of argument, clarity, organization, etc.

**Disability Resources:**
Washington University is committed to providing accommodations and/or services to students with documented disabilities. Washington University’s Cornerstone: Center for Advanced Learning Disability Resources is the University’s official resource for students with disabilities and students with suspected disabilities. DR assists students with disabilities by providing guidance and accommodations to ensure equal access to our campus, both physically and academically. To learn more about its services, initiate the process of formal documentation and/or to arrange for accommodations, please contact Disability Resources at the start of the course.

**Mental Health Resources:**
Mental Health Services’ professional staff members work with students to resolve personal and interpersonal difficulties, many of which can affect the academic experience. These include conflicts with or worry about friends or family, concerns about eating or drinking patterns, and feelings of anxiety and depression. See: http://shs.wustl.edu/MentalHealth.
Reporting Policies:
Please also review the CRTC website for policies regarding sexual assault reporting and reporting concerns about bias, prejudice or discrimination.