M19-512 Intermediate Biostatistics for Clinical Research (3 credit)

Fall 2022
Mondays and Wednesdays, 9:00 to noon
Taylor Avenue Building, 2nd floor, Doll & Hill

INSTRUCTORS: Yan Yan, MD, Ph.D
Professor of Surgery (Clinical epidemiology) and Biostatistics

TEACHING ASSISTANT: Nicole Ackermann, MPH.

OFFICE HOURS: By appointment with zoom meeting if in-person class not possible

PREREQUISITES: M19-511 or consent by instructor

TARGET AUDIENCE: medical students, clinicians, clinical and population health researchers

COURSE DESCRIPTION & OBJECTIVES: This course is a continuation of the introductory course (M19-511). The topics include basic statistical concepts and methods for various types of clinical data (continuous, categorical, count, and time-to-event outcome data). Through lectures, R labs, homework assignments, and in-class exam, students will learn the concepts and methods for those types of clinical outcome data, and will develop certain computing skills using R software.

COMPETENCIES: After completing the course, students should (1) understand the basic statistical concepts and methods for the four types of clinical outcome data, (2) be able to address clinical research questions using these concepts and methods, (3) be able to perform data analyses on these types of data with R software, and (4) be able to interpret the results in the context of clinical research.

GRADING
Your grade will be based on:
- Class participation (10%)
- HW 1 – HW 6: (50% total, each assignment 1/6*50%)
- In class exam (40%)

Grading Scale:
A+: 97-100; A: 93-96; A-: 90-92; B+: 87-89; B: 83-86; B-: 80-82; C+: 77-79; C: 73-76; C-: 70-72

ATTENDANCE AND PARTICIPATION

Class attendance is required. More than two unexcused absence from class result in 0 point from class participation.

POLICY ON LATE ASSIGNMENTS
Late assignments will result in a deduction of 20% of the assignment for each day late (including weekends) unless prior approval is obtained from the instructor or a compelling situation prevents prior approval (i.e. documented health issues or family emergencies).
<table>
<thead>
<tr>
<th>Class</th>
<th>Date</th>
<th>Topics/HW handout</th>
<th>Assignment Due</th>
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| 1     | 10/24| Course overview and simple linear regression (HW1 distributed on 10/19) |                  | DiMa: chap 13.1-13.3  
D&E: chap 7.3 |
| 2     | 10/26| Multiple linear regression HW2 |                  | DiMa: chap 13.4-13.5, 14.6  
D&E: chap 8.1-8.4 |
| 3     | 10/31| Diagnostics for linear regression model |                  | DiMa: chap 41.1-14.5  
D&E chap 8.5 |
| 4     | 11/02| Binomial distribution, maximum likelihood estimation, and simple logistic regression HW3 | HW1 | K&K: chap 4 |
| 5     | 11/7 | Multiple logistic regression |                  | K&K: chap 3. |
| 6     | 11/09| Assessing binary logistic regression models HW4 | HW2 | D&E: chap 9.4  
K&K: chap 9, 10 |
| 7     | 11/14| Logistic regression for case-control and matched designs |                  | DiMa: chap 9.1, 9.2, 9.7  
D&E: chap 9.5 |
| 8     | 11/16| Logistic regression for nominal outcome HW5 | HW3 | K&K: chap 12 |
| 9     | 11/21| Logistic regression for ordinal outcome |                  | K&K: chap 13 |
| 10    | 11/23| Poisson distribution, Poisson regression, over-dispersion HW6 |                  | D&E: chap 10.3.1, 10.5 |
| 11    | 11/28| Zero-inflated Poisson model | HW4 | Ref papers |
| 12    | 11/30| Introduction to survival analysis, KM method |                  | D&E: chap 15.1-15.3 |
| 13    | 12/05| Cox’s PHM | HW5 | D&E: chap 16.2.1, 16.2.2 |
| 14    | 12/07| Assessing Cox’s PHM |                  | D&E: chap 16.2.3, 16.2.4 |
| 15    | 12/12| Review for final exam | HW6 |                  |
| 16    | 12/14| In-class final exam |                  |                  |
Reference texts:
4. R package documents

DROP DATES
You may 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 MPHS Student Handbook. Late withdrawals will appear on your transcript as a withdrawal.

MPHS Academic Policy Guidelines:

Guidelines regarding MPHS course registration and enrollment, grades, tuition obligation, and academic leave are consolidated in the MPHS Student Handbook. Please review this document.

MPHS Guidelines for Academic and Non-Academic Transgressions:

By registering for this course you have agreed to the terms of the MPHS Academic Integrity Policy, outlined below and in more detail in the MPHS Student Handbook. Please review this policy before submitting your first graded assignment.

Academic Integrity/Plagiarism Policy:

- Academic dishonesty is a serious offense that may lead to probation, suspension, or dismissal from the University. Academic dishonesty includes plagiarism (the use of someone else’s ideas, statements, or approaches without proper citation). Academic dishonesty also includes copying information from another student, submitting work from a previous class for a new grade without prior approval from your instructor, cheating on exams, etc. You are responsible for reviewing WashU's academic integrity resources to become aware of all the actions that constitute academic dishonesty.
- All instances of academic dishonesty will be reported to the Office of the Registrar for investigation and potential disciplinary action. In addition, the instructor will make an independent decision about the student’s grade on any assignment in question. The MPHS process regarding academic dishonesty is described in the MPHS Student Handbook.

DISABILITY RESOURCES

It is the goal of Washington University to assist students with disabilities in removing the barriers their disabilities may pose and provide support in facing the challenge of pursuing an education at Washington University.

Washington University recognizes and accepts its professional, legal and moral responsibility to avoid discrimination in the acceptance and education of qualified students with disabilities and to provide reasonable accommodations to such students consistent with the principles embodied in the law. These guidelines apply to students seeking admittance as well as to those who become disabled while they are enrolled.

Washington University makes every effort to insure that all qualified applicants and students can participate in and take full advantage of all programs and opportunities offered within the university.
Washington University encourages and gives full consideration to all applicants for admission. Washington University does not discriminate in access to its programs and activities on the basis of age, sex, sexual orientation, race, disability, religion, color or national origin.

To learn more about services provided to students with disabilities, initiate the process of formal documentation and/or to arrange for accommodations, please review the Disability Resources for the Med School at the start of the course.

**MENTAL HEALTH**
Mental Health Services are available for full-time students enrolled on the Medical School campus. Students can make an appointment with Dr. Karen Winter (kwinters@wustl.edu) or through Student Health Services.

There are also contractual mental health service providers who are available off-campus. More information regarding this coverage and a list of participating providers are accessible via https://wusmhealth.wustl.edu/ and then clicking on Students and scrolling down to Mental Health Information https://wusmhealth.wustl.edu/students/mental-health-information/.

Please do not hesitate to reach out to Dr. Winters, 314-362-3523, or to any of our off-campus providers https://wusmhealth.wustl.edu/

**SEXUAL ASSAULT RESOURCES**
You can also speak confidentially and learn about available resources by contacting Dr. Gladys Smith, PhD, Sexual Violence Prevention Therapist and Licensed Psychologist at the Medical Campus, (314) 362-2404. Additionally, you can report incidents to the Office of Student Affairs or by contacting WUSM Protective Services 314-362-4357 or your local law enforcement agency.

**BIAS RESOURCES**
The University has a process through which students and staff who have experienced or witnessed bias, prejudice or discrimination against a student can report their experiences to the University’s Bias Report and Support System (BRSS) team. For details see: diversityinclusion.wustl.edu/brss/.

**Office of the Associate Vice Chancellor for Diversity, Equity and Inclusion (DEI)**
The DEI Training Team designs, facilitates and leads diversity education programming for faculty, staff and students on a wide range of topics including: creating a climate of respect, the value of diversity and the role of biases in our day-to-day lives.
diversity.med.wustl.edu/training/

The Office of Diversity Programs promotes diversity among and prepares medical students to lead in a global society. A priority for the Office of Diversity Programs is to cultivate and foster a supportive campus climate for students of all backgrounds, cultures and identities.
mddiversity.wustl.edu/

The Diversity and Inclusion Student Council promotes an inclusive campus environment for all School of Medicine students.
sites.wustl.edu/disc/

The Office for International Students and Scholars embraces the university’s mission of welcoming promising students from around the world.
wumma.wustl.edu/