



EPIDEMIOLOGY FOR CLINICAL RESEARCH

M88-588

Spring, 2019

Time: Mondays, 4:30 to 7:00 p.m.

Location: CRTC Center Classroom
2nd floor, Wohl Building

Instructor: Robert Fitzgerald, Ph.D., M.P.H.
Assistant Professor of Psychiatry (Child)
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Office Hours: By Appointment (Contact Dr. Fitzgerald directly)
Target audience: Graduate students, trainees, or junior faculty interested in conducting clinical research, including those enrolled in the Masters of Science in Clinical Investigation program and Applied Health Behavior Research program. Prior clinical research experience is helpful but not required.

Credits: 3

Course Overview

Introduction: This course introduces principles of epidemiology with the goal of applying epidemiologic methods to answer clinical research questions. The course provides basic tools used in descriptive and analytical epidemiology, which are crucial for making informed decisions in the care of patients as well as evaluating the epidemiologic literature. Critical thinking and scientific/analytic competencies are emphasized throughout the course.

Purpose: This course will focus on common applications of epidemiologic principles and tools in clinical research, in clinical issues, and in understanding the medical literature concerning these issues. This will be accomplished via different modalities that will enhance the critical thinking and scientific/analytic competencies for the students who complete the course.

Course Description

Course Format: The course format will include lectures, class discussion, problem sets, supplementary reading material, critiquing a research study, and a final exam.

Course Elements and Requirements for Students:

- It is very important that students attend all classes. The information needed to master the course objectives will be presented and discussed in class. Students who miss three or more classes may be asked to withdraw from the course and to re-take the course at a later time. Arrangements for assignments that will be missed due to travel/conferences, etc. must be made ahead of the expected missed class.
- Students are expected to complete the assigned readings before each lecture. The readings have been selected to complement the lectures, and will provide additional examples for applying basic epidemiologic methods and tools in clinical research.
- Students should be prepared to discuss the exercises and any assigned readings at the start of each class and to participate in class discussion.
- Students are required to complete a written critique of a published research study.

Course Elements and Requirements for the Instructors:

- The instructor will usually be available during normal business hours to answer any questions that you may have about the course. If your schedule precludes you from meeting during normal business hours, he will make every effort to meet with you at times that may be more convenient for you. Please feel free to contact the instructor by telephone or via email to discuss any issues concerning the course.

- The instructor retains the right to change the order of the lectures and the content of the class to meet the needs of the students who are enrolled in the course.

Texts:

Gordis, Leon. Epidemiology. (5th edition). Elsevier Saunders, Philadelphia, 2014. (**required text**)

Fletcher RH, Fletcher SW, Fletcher GS. Clinical epidemiology. The essentials (5th edition). Lippincott Williams & Wilkins, Philadelphia, 2014. (optional text)

Assigned weekly readings: Articles or book chapters will be emailed or posted on Blackboard. These articles are intended to supplement the text and are required to be read by all students.

Grading Determination and Policy: Each student will complete a 2-page written critique of a study (30%), 4 short problem sets (30%), and a comprehensive final exam (40%). The instructor will assign each student to critique a specific study. Each Problem Set will cover material from 2-3 class sessions and will be posted on Canvas a week before the due date. Late submissions (problem sets and critiques) will not be accepted, and critiques that are not completed independently by the student will not be graded.

The critique of the published study (30%) will be based on the following criteria. Please use the following separate headings in your critique.

- 1) Study objective, setting and participants (5 points).
- 2) Description of the study design (5 points).
- 3) Brief description of the study results and its implications (5 points).
- 4) Strengths and weaknesses of the study identified by you and by the authors (5 points).
- 5) How these weaknesses of the study affected the findings (15 points).
- 6) How the authors addressed the weaknesses of the study (10 points).
- 7) How the study could be improved (15 points)

For items 4-7, focus your critique on the issues of selection bias, measurement bias, confounding, and any other methodological issues pertaining to the type of study design used in the study that were discussed during class. Please use a narrative style to write your critique and submit via Canvas by the assigned due date.

Grading scale

| Grades/sub-grades |
|---|
| A (93% to 100%) A- (90% to 92%) |
| B+ (88% to 89%) B (83% to 87%) B- (80% to 82%) |
| C+ (77% to 79%) C (73% to 76%) C- (70% to 72%) |

Academic Integrity Policy

Students are expected to abide by and uphold the Academic Integrity Policy for Graduate Students from the Graduate School of Arts & Sciences. All students should have received this policy. Please contact the Office of the Dean of the School of Arts & Sciences to obtain copies of this document.

Pagers and cellular phones

Although clinicians may be expected to be available by pager or cellular phone, please limit their use as much as possible during class.

Students with disabilities

Washington University is committed to providing accommodations and/or services to students with documented disabilities. Students who are seeking support for a disability or a suspected disability should contact the Disability Resource Center (DRC) at 314-935-5970 or disabilityresources@wustl.edu. The DRC is responsible for approving and arranging all accommodations for University Students.

Accommodations based upon sexual assault:

The University is committed to offering reasonable academic accommodations to students who are victims of sexual assault. Students are eligible for accommodation regardless of whether they seek criminal or disciplinary action. Depending on the specific nature of the allegation, such measures may include but are not limited to: implementation of a no-contact order, course/classroom assignment changes, and other academic support services and accommodations. If you need to request such accommodations, please direct your request to one of following resources: Dr. Karen Winters, MD, Director of Student Health Service; Dr. Gladys Smith, PhD, Sexual Violence Prevention Therapist and Licensed Psychologist, or Kim Webb, Director of the Relationship and Sexual Violence Prevention Center at the Danforth Campus. These are confidential resources; however, requests for accommodations will be shared with the appropriate University administration and faculty. The University will maintain confidential any accommodations or protective measures provided to an individual student so long as it does not impair the ability to provide such measures.

If a student comes to me to discuss or disclose an instance of sexual assault, sex discrimination, sexual harassment, dating violence, domestic violence or stalking, or if I otherwise observe or become aware of such an allegation, I will keep the information as private as I can, but as a faculty member of Washington University School of Medicine, I am required to immediately report it to an Office of Education Dean or directly to Ms. Jessica Kennedy, the University's Title IX Director. If you would like to speak directly with Ms. Kennedy, she can be reached at (314) 935-3118, or by visiting the Title IX office in Umrath Hall on Danforth Campus. Additionally, you can report incidents or complaints to the Office of Student Affairs or by contacting WUSM Protective Services 314-362-4357 or your local law enforcement agency.

You can also speak confidentially and learn more about available resources by contacting Dr. Gladys Smith, PhD, Sexual Violence Prevention Therapist and Licensed Psychologist at the Medical Campus, (314) 362-2404, or contacting the Relationship and Sexual Violence Prevention Center located on the 4th floor of Seigle Hall on Danforth Campus, (314) 935-3445.

For further Resources, see: wusmhealth.wustl.edu/students/victims-sexual-assault-abuse/resources-2/

Bias Reporting:

The University has a process through which students, faculty, staff and community members who have experienced or witnessed incidents of bias, prejudice or discrimination against a student can report their experiences to the University's Bias Report and Support System (BRSS) team.

See: diversityinclusion.wustl.edu/brss/. To report mistreatment or offensive behavior in the MD program, please report via the following pathways:

- CANVAS (the Learning Management System) utilizing the direct link from the Student Commons < Mistreatment, Offensive Behavior, and Bias Reporting
- Directly contacting any of the following individuals:
 - Senior Associate Dean for Education
 - Associate Dean for Student Affairs
 - Associate Dean for Medical Student Education
 - Student Ombudsperson (as another confidential resource)

Mental Health:

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: shs.wustl.edu/MentalHealth

On the Medical Campus:

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.

mdiversity.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/

Course Calendar

| Date | Week | Material |
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| 1/14 | 1 | Topic: Introduction and Course Overview Readings: Gordis Chapter 1 |
| 1/28 | 2 | Topic: Measurement of Morbidity and Mortality Readings: Gordis Chapter 3 & 4 |
| 2/4 | 3 | Topic: Natural Hx of Disease/Prevention/Prognosis Readings: Gordis Chapter 6 <i>* Problem Set 1 due</i> |
| 2/11 | 4 | Topic: Causality Readings: Gordis Chapter 14 Rothman, K. J., & Greenland, S. (2005). Causation and causal inference in epidemiology. <i>Am J Public Health, 95 Suppl 1, S144-150.</i> |
| 2/18 | 5 | Topic: Study Design Basics Readings: Gordis Chapter 8 (pgs. 155 – 160) <i>* Problem Set 2 due</i> |
| 2/25 | 6 | Topic: Risk Readings: Gordis Chapter 11 & 12 |
| 3/4 | 7 | Topic: Case-Control Designs Readings: Gordis Chapter 10 <i>* Problem Set 3 due</i> |
| 3/11 | 8 | SPRING BREAK – no class this week |
| 3/18 | 9 | Topic: Cohort studies Readings: Gordis Chapter 9 Vandembroucke JP, von Elm E, Altman DG, Gøtzsche PC, Vandenbroucke JP, von Elm E, Altman DG, Gøtzsche PC, Multon CD, Poole C, Schlesselman JJ, Egger M, for the STROBE initiative. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: Explanation and elaboration. <i>PLoS Med</i> 4(10):e297, 2007 |
| 3/25 | 10 | Topic: Randomized Controlled Trials (RCTs) Readings: Gordis Chapters 7 & 8 (pgs. 161 – 174) Moher D, Hopewell S, Schulz KF, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. Details of CONSORT guidelines from www.consort-statement.org |
| 4/1 | 11 | Topic: Interpreting Epi Data/Bias Analysis Readings: Gordis Chapter 15 |

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| 4/8 | 12 | Topic: Reviewing and critiquing scientific literature <i>Guest Lecture: TBD</i> <i>* Problem Set 4 due</i> |
| 4/15 | 13 | Genetic and Molecular Epidemiology Readings: Gordis Chapter 16 |
| 4/22 | 14 | Topic: Infectious Disease Epidemiology OR Health Services Research Readings: Gordis Chapter 2 OR Chapter 17 |
| 4/29 | 15 | Final Exam |
| 5/2 | 16 | Article Critique due |