Epidemiology for Clinical Research

M88-588

Spring, 2017

Time: Monday, 4:30-7:00 p.m.

Location: Classroom, Clinical Research Training Center
2nd floor of the Wohl Clinic Building

Instructor: Lauren Garfield, Ph.D., M.P.H.
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Office Hours: By Appointment (Contact Dr. Garfield 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 the Applied 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 venues 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 of supplementary reading material, a lab, quizzes, critiquing a research study, and a small study project.

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 quizzes or 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 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. Students are also required to develop a small study proposal as described in more detail in the "grading determination and policy" section.

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, she 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.

Textbook:

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

Assigned weekly readings: Articles can be obtained from the Blackboard course site. These articles are intended to supplement the text and are required to be read by all students.

GRADING DETERMINATION AND POLICY

Quizzes (20%)
A total of 4 quizzes will be administered via Blackboard. Quizzes will be available for approximately 1 week and must be completed during one sitting. Each quiz will consist of 5-10 questions. Quizzes may be completed using course notes, the textbook, and materials available on Blackboard. However, students cannot use the assistance of another human being (even via the internet).

Lab Assignment (15%) 2/13/2017
The lab assignment is meant to serve as an applied assignment to familiarize students with calculating and interpreting common epidemiologic measures. The lab will serve as a course lecture for that day. It can be completed alone or with a partner. If submitting with a lab partner, please include both students' names on the document. Both students will receive the same grade for the lab.

Manuscript Critique (30%)
Each student will complete a critique of a peer-reviewed journal article. **The article will be made available later in the course.**
The critique of the published study 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 (5points).
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

Study Proposal (30%)

The 3-page study proposal is based on the format from the National Institutes of Health. It will only include the technical part of the proposal (budgets, biosketches, etc. are not required). The main subject headings for a study proposal are:

a) Specific Aims (no more than ½ page),
b) Significance (no more than ¼ page),
c) Innovation (no more than ¼ page)
d) Research Design and Methods (about 2 pages).

Preliminary Studies and Power and Sample Size sections are not required. Please complete the **Bias Form** that describes how bias may play a role in your proposed study. Please use 0.5 inch margins throughout and Arial 11 font size. **An evidence-based guide to writing study proposals for clinical research can be found on Blackboard.** Each student will be required to do each of the following items:

Submit drafts by email to Dr. Garfield of:

• Specific Aims, Significance, and Innovation (due 3/13/2017)
• Research Design and Methods section (due 4/10/2017)

The final written proposal of the Specific Aims, Significance, Innovation, and the Research Design/Methods sections, **due 5/5/2017**, will constitute 30% of the final grade. I will provide you with comments on each section of the proposal prior to final submission for grading and return them to you in a timely manner to enable you to revise your proposal. Please also describe how you addressed each of the comments throughout your revisions using Track Changes and the "comment" facility in Microsoft Word. You are encouraged to select a topic that relates to your current or proposed area of interest. Late submissions will not be accepted, and proposals that are not completed independently by the student will not be graded.

Lead a Discussion/Participation (5%)
Students are expected to attend class and actively participate in in-class activities. Two and one half hours is a lot of lecture time, so I find it more interesting to break things up with discussion and activities. During the first class, each student will sign-up to lead the class discussion for one of the assigned readings. This will involve paying extra attention to the details of the assigned reading and being prepared to lead the class discussion for 10-15 minutes. This could involve a power point presentation, but it does not have to. My suggestion would be to use these presentations as practice for your manuscript critique and discuss the 7 criteria listed previously. Be creative and get your classmates involved in the discussion! My intention with including this assignment is to give everyone an easy opportunity to earn a full 5% and make class more interesting.

Grades will be determined based on the following scale:

Percentage Points	Letter Grade
93-100	A
90-92.99	A-
88-89.99	B+
83-87.99	B

80-82.99	B-
77-79.99	C+
73-76.99	C
70-72.99	C-
Below 70	F

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 5-4062 on the lower level of the Women's Building (drc@dosa.wustl.edu). The DRC is responsible for approving and arranging all accommodations for University students.

Acknowledgements
The Instructor would like to acknowledge Drs. Anjali Deshpande and Erik Nelson for the use of their intellectual property in this course.

Course Calendar

Date	Week	Materials
1/23	1	**Topic: Introduction and Course Overview** **Readings:** Fletcher Chapter 1 Sackett DL. Clinical epidemiology: what, who, and whither. J Clin Epidemiol 55, 1161-1166, 2002. Reisch LM, Fosse JS, Beverly K, et al. Training, quality assurance, and assessment of medical record abstraction
1/30	2	**Topic: Determining a diagnosis** **Readings:** Fletcher Chapter 8 Feinstein AR. Misguided efforts and future challenges for research on diagnostic tests. J Epidemiol Community Health 56, 330-332, 2002. Colditz GA. Improving standards of medical and public health research. J Epidemiol Community Health 56, 333-334, 2002. Choi BCK. Future challenges for diagnostic research: striking a balance between simplicity and complexity. J Epidemiol Community Health 56, 334-335, 2002. Coughlin SS. Future challenges for research on diagnostic tests: genetic tests and disease prevention. J Epidemiol Community Health 56, 335-336, 2002. ***Assigned: Quiz 1**
2/6	3	**Topic: Measurement in Epidemiology and Frequency of disease** **Readings:** Fletcher Chapters 2 and 3 Gordis Chapter 3 (BlackBoard) ****Due: Quiz 1**
2/13	4	**Lab 1** - Can be completed alone or in groups of 2 during class time or outside of class time. ****Class will not meet this week.****
2/20	5	**Topic: Causality** **Readings:** Fletcher Chapter 12 Rothman, K. J., & Greenland, S. (2005). Causation and causal inference in

		epidemiology. *Am J Public Health, 95 Suppl 1*, S144-150. ****Due: Lab 1**
2/27	6	**Topic: Risk of disease** **Readings:** Fletcher Chapter 4 Katz DL. Clinical epidemiology and evidence-based medicine, Chapter 5 – Measuring and conveying risk. ***Assigned: Quiz 2**
3/6	7	**Topic: Cohort studies** **Readings:** Fletcher Chapter 5 White E, Hunt JR, Casso D. Exposure measurement in cohort studies: The challenges of prospective data collection. Epi Reviews 20, 43-56, 1998. Vandenbroucke JP, von Elm E, Altman DG, Gotzsche PC, Multow CD, Poole C, Schlesselman JJ, Egger M, for the STROBE initiative. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: Explanation and elaboration. PloS Med 4(10):e297, 2007 ****Due: Quiz 2**
3/13	8	**SPRING BREAK** – no class this week ****Due: Draft of first sections of study proposal****
3/20	9	**Topic: Reviewing and critiquing scientific literature** *Guest Lecture: Alexis Duncan,Ph.D., M.P.H., The Brown School* ***Assigned: Manuscript critique**
3/27	10	**Topic: Prognosis of disease** **Readings:** Fletcher Chapter 7 Sackett DL, Haynes RB, Guyatt GH, Tugwell P. Clinical epidemiology. Chapter 6 – Making a prognosis. ****Due: (4/2 by midnight) Manuscript Critique** ***Assigned: Quiz 3**
4/3	11	**Topic: Treatment I** **Readings:** Fletcher Chapter 9

		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 ****Due: Quiz 3**
4/10	**12**	**Topic: Treatment II** **Readings:** Juni P, Altman DG, Egger M. Systematic reviews in healthcare: Assessing the quality of controlled clinical trials. BMJ 323, 42-46, 2001. Black HR, Crocitto MT. Number needed to treat: Solid science or a path to pernicious rationing? Am J Hypertens 11, 128S-134S, 1998. Hollis S, Campbell F. What is meant by intention to treat analysis? Survey of published randomized controlled trials. BMJ 319, 670-674, 1999. ****Due: draft of second sections of study proposal****
4/17	**13**	**Topic: Studying cases** **Readings:** Fletcher Chapter 6 Wacholder S, McLaughlin JK, Silverman DT, Mandel JS. Selection of controls in case-control studies. I. Principles. Am J Epidemiol 135, 1019-1028, 1992. Wacholder S, Silverman DT, McLaughlin JK, Mandel JS. Selection of controls in case-control studies. II. Types of controls. Am J Epidemiol 135, 1029-1041, 1992. ***Assigned: Quiz 4**
4/24	**14**	**Topic: Statistical methods in epidemiology** **Readings:** Grobbee DE & Hoes AW: Chapter 12 - Clinical epidemiological data analysis.
5/1	**15**	**Topic: Bias Analysis/Modern Methods** **Readings:** Lash chapters 2-3 Diez-Roux AV. Multilevel analysis in public health research. Annu Rev Public Health 21, 171-192, 2000. Sternthal MJ, Jun H0J, Earls F, Wright RJ. Community violence and urban childhood asthma: A multilevel analysis. J Eur Resp Soc 2010. ****Due: Quiz 4** ****Due Final study proposal (May 5, 2017)**