

**CLINICAL MEASUREMENT AND EVALUATION
EPID 711, PUBH 760**

Fall Semester, 2015

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Office Hours: By appointment

TAs:

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Time: 2:00 – 3:15; Tuesday and Thursday
TA Review Session – To be announced

Place: G100 Bondurant

Website: sakai.unc.edu If you are registered for the class, use your ONYEN. If you are auditing, please provide me with your email address so that we may add you to the list on Sakai.

Objectives: Provide a broad-based introduction to the concepts and methods of epidemiology with particular emphasis on their application in clinical research, clinical practice and health care policy.

Lectures: The lectures are the core of the course. The lectures are intended to be participatory. I give many examples and ask for thoughtful answers to questions. It is more important that you speak up and give a reasonable answer than to be right. Many times, an incorrect answer provides greater learning opportunities than just giving the right answer. I encourage **everyone** to participate.

Handouts are provided for each lecture. Often, answers to the questions asked during the lecture are provided in the handout. It is up to you whether you read through the handouts ahead of time. Reading through the handouts ahead of time will give you an idea of what we'll be covering in class and will also give you many of the answers to questions given in class. But coming in without looking ahead of time will allow you to think more about the answer during class. Try not to look at the answers during class!!! In any case, I encourage everyone to review the handouts thoroughly after class.

The handouts do not provide the answers to every question asked in class or to every question posed in the handout. This omission is intentional. Learning is a multi-sensory task. Actively taking notes is one way to enhance learning. If something is unclear in class, feel free to ask! Class attendance is essential to maximize your learning in this class, especially given the lack of an appropriate comprehensive textbook for the material.

A common mistake is to come to class, take notes, and then close your notebook and wait for the next class. I would much prefer that you spend the time that you would have spent reading or preparing for the next class, reviewing the material from the last class. In other words, after each class, spend at about 1 hour reviewing the content, filling in the gaps in the notes, re-doing the calculations. If you do this in a group, it will be even better.

If you miss a class, you should find someone who went to class and review their notes. If you are still uncertain about the material, contact a TA for a review.

TA Sessions: TA Sessions will be held weekly. These sessions will be used to review the covered material, to answer questions about problem sets, and to review the answers to problem sets after grading. These sessions should be your primary source for answers to questions. In addition, you may contact the TAs directly by e-mail, and if necessary, we will establish office hours for the TAs.

Handouts: Handouts will be posted on the class website for downloading a minimum of 2 days before a class. If access to the handouts on the web is a problem, please let one of the TAs or myself know.

Texts: Recommended: Szklo & Nieto, Epidemiology: Beyond the Basics, 2nd edition

<http://www.epidemiolog.net/evolving/>
Rothman, Epidemiology: An Introduction
Sackett, Clinical Epidemiology
Hennekens, Epidemiology in Medicine

Also recommended: Rothman & Greenland, Modern Epidemiology
Fletcher, Fletcher and Wagner, Clinical Epidemiology, 3rd edition
Hulley, Cummings. Designing Clinical Research
Norman, Streiner. Biostatistics: The Bare Essentials

Additional Readings: Occasionally, articles may be placed on the website approximately 1 – 2 weeks prior to a lecture.

Study Groups: Study groups are strongly encouraged. If you would like to be in a group, and do not have someone to work on problem sets with or review notes, then let us know and we will try to find others in a similar situation – or find an existing group willing to take on another member.

Grades: The course grades are based on six problem sets (60%) and a final examination (40%).

Only five problem sets will contribute to the grade. You may choose to skip one problem set or you may drop your lowest grade.

Final grades are based on the standard graduate school scale (H,P,L,F). The breakdown is H: $\geq 95\%$; P: 70 – 94%; L: 65 – 70%; F: $< 65\%$. The score will be calculated as $0.60 \times \text{mean}(5 \text{ highest problem sets}) + 0.40 \times (\text{final exam grade})$ with the following caveat: all students **must** receive at least 50% on the final examination. A score of $< 60\%$ on the final examination will result in an L if the overall point score is $\geq 65\%$ or an F if the overall point score is $< 65\%$.

Incompletes will be given under special circumstances agreed upon by the student and instructor.

Please try not to worry too much about your grade. This course is about learning the material. It is not about the grades. With each problem set, I give an answer key. These keys are critical to your learning. Unfortunately, we don't have enough time in class to go through the problem sets. You can learn a lot by looking at what you missed and what you got right, but were uncertain about.

Take home problem sets: Each problem set comprises 5 - 10 problems. Problem sets are based on the lectures and occasionally on supplemental reading. Problem sets are typically handed out one week before they are due. You are strongly encouraged to begin working on them when they are made available. But if you attempt something and it seems foreign, stop working on that problem. It just means it hasn't been covered yet.

Problem sets are intended to be a major part of the learning experience in this class. You are expected to complete and turn in your own problem set. You may discuss and work through the problems with other students in the class. **Direct sharing of answers (I'll do this one, you do**

that one) is an honor code violation. Use of problem sets from previous years is also an honor code violation.

You may use computer software when completing the problem sets. Excel or another spreadsheet program can be very helpful when making calculations. If you are not familiar with Excel, I strongly encourage you to become familiar with it. We will hold one session early in the semester to introduce Excel to novices. Stata or SAS may also be used if you find them helpful.

For problem sets and the final: Be precise! Be concise! – Points may be taken off for verbosity and incorrect or irrelevant information (the write everything you think you know about the subject in hopes that some of it will be correct phenomenon).

You are expected to show your work for the problem sets. Points may be deducted if you have not shown the work. Showing your work means: a) writing the formula used for a calculation, b) showing the numbers substituted into the formula, c) showing appropriate intermediate calculations in multi-step calculations (e.g. if you need to calculate a confidence interval that requires you to calculate a variance first, you should also show the calculation of the variance), and d) showing the answer. You must also record the appropriate units, including the time frame for calculations using incidence proportions (cumulative incidence).

Problem sets are due to the TAs at the start of class. Points will be deducted for handing in problem sets late, unless permission is obtained ahead of time (5% if turned in 1 day late; 10% 2 - 3 days late; 15% beyond that).

You are *encouraged* to use a word processor for the problem sets whenever possible. The problem sets are provided in Word format on the website to facilitate completing the problem sets electronically. Please be sure that the question is re-stated on your written assignments.

Take home final examination: The final examination will be comprehensive, including material from the entire course. Most of the problems will be comparable to those on the problem sets. The exam will be distributed on 12/1/2015 and will be due 12/7/2015. The exam is to be completed independently, without assistance from other students. **It is an honor code violation to use exams from previous years or consult in any way with other students (current or past).**

Grading Complaints: If you have a complaint about a grade or grading of a question, submit the complaint in writing and I will consider it.

Cheating: We take cheating very seriously. You may work together on problem sets. However, each person should attempt each problem and will be expected to turn in his/her own problem set. The final examination **must** be your own work. Cheating on the final examination will result in referral to the appropriate University disciplinary court.

The Instrument of Student Judicial Governance, which contains the provisions of the Honor Code, states that students have four general responsibilities under the Code:

1. Obey and support the enforcement of the Honor Code;
2. Refrain from lying, cheating, or stealing;
3. Conduct themselves so as not to impair significantly the welfare or the educational opportunities of others in the University community; and
4. Refrain from conduct that impairs or may impair the capacity of University and associated personnel to perform their duties, manage resources, protect the safety and welfare of members of the University community, and maintain the integrity of the University.

The Honor System's "Honor in the Syllabus" page includes the following suggested "affirmation of the Honor Code":

The University of North Carolina at Chapel Hill has had a student-administered honor system and judicial system for over 100 years. The system is the responsibility of students and is regulated and governed by them, but faculty share the responsibility. If you have questions about your responsibility under the honor code, please bring them to your instructor or consult with the office of the Dean of Students or the Instrument of Student Judicial Governance. This document, adopted by the Chancellor, the Faculty Council, and the Student Congress, contains all policies and procedures pertaining to the student honor system. Your full participation and observance of the honor code is expected.

In addition, the Honor System suggests that all written work should be submitted with the following pledge: "On my honor, I have neither given nor received unauthorized aid on this assignment."

Schedule:

<i>Date</i>	<i>Lecture</i>	<i>Topic</i>	<i>Instructor</i>	<i>Assignments</i>
18-Aug	1	Introduction/ Measures of disease	Miller	
20-Aug	2	Probability and Odds	Miller	
25-Aug	3	Measures for Diagnosis – Basics	Miller	
27-Aug	4	Measures of Frequency	Miller	
1-Sep	5	Measures of Association	Miller	
3-Sep	6	Measures of Impact	Miller	Problem Set 1 - due
8-Sep	7	Statistical tests, p-values, and confidence intervals	Miller	
10-Sep	8	Standardization	Miller	
15-Sep	9	Etiology/Causation	TA	
17-Sep	10	Screening	TA	Problem Set 2 - due
22-Sep	11	Study Design: Overview	Miller	
24-Sep	12	Clinical Trials 1	Miller	
29-Sep	13	Clinical Trials 2	Miller	
1-Oct	14	Clinical Trials 3/Cohort Studies	Miller	
6-Oct	15	Case Control Studies 1	Miller	
8-Oct	16	Case Control Studies 2	Miller	Problem Set 3 - due
13-Oct	17	Cohort Studies	TA	
15-Oct		NO CLASS – Fall Break		
20-Oct	18	Cross-sectional Studies; Ecological Studies	TA	
22-Oct	19	Measurement bias	Miller	Problem Set 4a - due
27-Oct	20	Interaction/Effect measure modification – 1 & 2	Miller	
29-Oct	21	Confounding 1	Miller	Problem Set 4b - due
3-Nov	22	Confounding 2 (DAGs)	TA	
5-Nov	23	Overview of Regression Techniques – 1	Miller	
10-Nov	24	Overview of Regression Techniques – 2	Miller	
12-Nov	25	Diagnosis - likelihood ratios	Miller	Problem Set 5- due
17-Nov	26	Diagnosis – likelihood ratios II; ROC curves	Miller	
19-Nov	27	Diagnosis - study design; bias	Miller	
24-Nov	28	Diagnosis – bias, part 2	Miller	
26-Nov		NO CLASS – Thanksgiving		
1-Dec	29	Problem Set Review; Wrap-up	TA	Problem Set 6 – due; Final Exam - Distributed
7-Dec		FINAL DUE		Final Examination – Due